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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

[Docket No. 02-088-1]

RIN 0579-AB47

Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are establishing, by regulation, standards and procedures governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. This action is necessary to protect animal and plant health, and animal and plant products.

DATES: This interim rule is effective on [Insert date 60 days after date of publication in the Federal Register]. We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02-088-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 02-088-1. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 02-088-1" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the Federal Register, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: For information concerning the regulations in 7 CFR part 331, contact Dr. Robert Flanders, Chief, Pest Permit Evaluations Branch, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236, (301) 734-5930.

For information concerning the regulations in 9 CFR part 121, contact Dr. Denise Spencer, Senior Staff Veterinarian, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231, (301) 734-3277.

SUPPLEMENTARY INFORMATION:

Background

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). Title II of Public Law 107-188, "Enhancing Controls on Dangerous Biological Agents and Toxins" (sections 201 through 231), provides for the regulation of certain biological agents and toxins by the Department of Health and Human Services (subtitle A, sections 201-204) and the Department of Agriculture (subtitle B, sections 211-213), and provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). Subtitle D (section 231) provides for criminal penalties regarding certain biological agents and toxins. For the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC) has been designated as the agency with primary responsibility for implementing the provisions of the Act; the Animal and Plant Health Inspection Service (APHIS) is the agency fulfilling that role for the Department of Agriculture (USDA).

In subtitle B (which is cited as the "Agricultural Bioterrorism Protection Act of 2002," referred to below as the Act), section 212(a) provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that she determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act further requires (under section 213(b)) that all persons in possession of any listed biological agent or toxin must, within 60 days of the publication of that interim rule, notify the Secretary of such possession.

In accordance with these statutory requirements, on August 12, 2002, we published in the Federal Register (67 FR 52383-52389, Docket No. 02-082-1) an interim rule that established the

initial lists of biological agents and toxins and set out the manner in which persons in possession of listed agents and toxins were to provide notice of such possession. To accomplish this, we established two new parts in the Code of Federal Regulations (CFR), one part in the plant-related provisions of title 7, chapter III, and one part in the animal-related provisions of title 9, chapter I. Each part was constructed similarly, with a section that provided definitions for specific terms used in the part, a section that set out the list of biological agents and toxins, and a section that provided guidance on the manner in which notice of possession was to be provided. On September 26, 2002, we published a technical amendment to the interim rule (67 FR 60519-60520, Docket No. 02-082-2) in which we updated the definitions of biological agent and toxin in each part.

Under section 212 of the Act, the Secretary must also provide by regulation for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of listed biological agents and toxins in order to protect animal and plant health, and animal and plant products. Specifically, sections 212(b) and (c) require that the Secretary:

- Establish and enforce safety procedures for listed agents and toxins, including measures to ensure proper training and appropriate skills to handle agents and toxins, and proper laboratory facilities to contain and dispose of agents and toxins;
- Establish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose;
- Establish procedures to protect animal and plant health, and animal and plant products, in the event of a transfer or potential transfer of a listed agent or toxin in violation of the safety procedures and safeguard and security measures established by the Secretary; and

- Ensure appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

This interim rule establishes the regulations required under the Act. To accomplish this, we are amending 7 CFR part 331 and 9 CFR part 121. First, we are changing the title of both parts from "Possession of Biological Agents and Toxins" to "Possession, Use, and Transfer of Biological Agents and Toxins" to indicate the expanded scope of the regulations. Second, we are adding and removing definitions in §§ 331.1 and 121.1, as detailed below. Third, we are moving the lists of biological agents and toxins out of §§ 331.2 and 121.2 and adding in their place a new section that sets out the purpose and scope of each part. Fourth, we are removing the notification requirements in §§ 331.3 and 121.3, which are no longer applicable, and placing the lists of biological agents and toxins in those sections. We are amending both lists, as discussed below, and moving the exemption provisions found in the original § 121.2 to a new section, § 121.4. Finally, we are adding new sections that set out the effective dates, exemptions, registration requirements, responsibilities of the responsible official, safety and security requirements, transfer requirements, and appeals process. These new sections are discussed in detail below.

Effective and Applicability Dates

Both 7 CFR part 331 and 9 CFR part 121 begin with sections that discuss the effective dates of the regulations, §§ 331.0 and 121.0, respectively. Pursuant to section 213(c) of the Act, the Secretary must, not later than 180 days after the Act's enactment, promulgate an interim final rule establishing the standards and procedures governing the possession, use, and transfer of listed biological agents and toxins that shall take effect 60 days after the date on which the rule is promulgated. However, the Act also requires that the interim final rule include timeframes for

the applicability of the rule that minimize disruption of research or educational projects that involve biological agents or toxins listed pursuant to section 212(a)(1) and that were underway as of the effective date of such rule.

Accordingly, in 7 CFR 331.0 and 9 CFR 121.0 we provide that the regulations in both parts are effective on [Insert date 60 days after date of publication in the Federal Register]. On and after that date, any individual or entity possessing, using, or transferring any listed agent or toxin must be in compliance with the provisions of each part.

However, to minimize the disruption of research or educational projects (e.g., teaching demonstrations) involving listed agents or toxins that were underway as of the effective date of these regulations, we provide that any individual or entity possessing such agents or toxins as of the effective date (current possessors) will be afforded additional time to reach full compliance with the regulations in each part. Any provision not specifically cited in paragraphs (a) through (f) of 7 CFR 331.0 and 9 CFR 121.0 will applicable as of [Insert date 60 days after date of publication in the Federal Register].

In recognition of the potential delays in registering individuals and entities under these regulations during the first year of implementation and the subsequent delay of research, we will also afford additional time to reach full compliance with the regulations to individuals and entities who do not currently possess listed agents or toxins. Therefore, we provide that any individual or entity who does not possess listed agents or toxins by the effective date of these regulations, but who wishes to initiate a research or educational project prior to November 12, 2003, must be in compliance with the provisions of these regulations that are applicable for current possessors at the time of application, as provided in paragraphs (a) through (e) of 7 CFR 331.0 and 9 CFR 121.0.

In paragraph (a) of both parts, we set forth the transfer provisions that will be applicable during the phase-in period. Specifically, we provide that, during the period from [Insert date 60 days after date of publication in the Federal Register], to November 12, 2003, listed agents or toxins may only be transferred to an individual or entity that is not registered under 7 CFR part 331 or 9 CFR part 121 if the individual or entity has been issued a permit by the APHIS Administrator (the Administrator) under 7 CFR part 330 or 9 CFR 122 to import or move interstate that specific agent or toxin. Since some individuals or entities may not have been issued a permit prior to the effective date of these regulations, we further provide that an individual or entity may apply for a permit. In addition to the permit required under 7 CFR part 330 or 9 CFR 122, an individual or entity will also be required to submit APHIS Form 2041, in accordance with §§ 331.13(c) and 121.14(c), respectively.

Because USDA permits do not cover intrastate movement, an individual or entity may not receive a listed agent or toxin that is being moved intrastate until that individual or entity is registered in accordance with 7 CFR part 331 or 9 CFR part 121.

With regard to overlap agents and toxins, we provide that from [Insert date 60 days after date of publication in the Federal Register], to November 12, 2003, listed overlap agents or toxins may only be transferred to an individual or entity not registered under 9 CFR part 121 using the permit provisions described above or, if the individual or entity is registered under CDC's select agent program for that specific overlap agent or toxin, in accordance with CDC's regulations in 42 CFR part 72. The regulations in 42 CFR part 72 cover all inter-entity transfers of "select agents," which include overlap agents and toxins, whether interstate or intrastate. We note, however, that CDC's regulations in 42 CFR part 72 will be superceded by CDC's new select agent regulations in 42 CFR part 73 on March 12, 2003, and, thereafter, listed overlap

agents or toxins may be transferred to an individual or entity not registered under 9 CFR part 121 or 42 CFR part 73 using the permit provisions described above.

In paragraph (b) of both parts, we require that the responsible official submit the registration application package by March 12, 2003, as required in 7 CFR 331.8 and 9 CFR 121.9. In addition, we require that the responsible official submit to the United States Attorney General (the Attorney General) the names and identifying information for the responsible official; alternate responsible official, where applicable; entity; and, where applicable, the individual who owns or controls the entity.

Paragraph (c) of both parts requires the responsible official to submit to the Attorney General by April 11, 2003, the names and identifying information for all individuals whom the responsible official has identified as having a legitimate need and the appropriate training and skills to handle or use listed agents or toxins. We note that these individuals must have received appropriate training in biosafety and/or containment, in accordance with 7 CFR 331.12 or 9 CFR 121.13.

We recognize that developing and implementing the security section of the Biocontainment and Security Plan (7 CFR 331.11) or the Biosafety and Security Plan (9 CFR 121.12) may require additional time to consult with security experts and to obtain the necessary funding. Therefore, in paragraph (d) of both parts, we provide that the responsible official will have until June 12, 2003, to submit the security section of the plan to APHIS or, for overlap agents or toxins, to APHIS or CDC. Then the responsible official has until September 12, 2003, to implement that security plan and provide security training in accordance with 7 CFR 331.12 or 9 CFR 121.13.

Finally, by November 12, 2003, the registration application process must be complete and the entity must be in full compliance with the regulations.

Definitions

In 7 CFR 331.1 and 9 CFR 121.1, we define the terms used in the regulations. In our August 2002 interim rule establishing the regulations, we defined the terms biological agent, facility, person, responsible facility official, and toxin in both parts, while the term overlap agent or toxin was defined only in 9 CFR 121.1 (this term is not applicable to the plant-related regulations in 7 CFR part 331).

In this interim rule, we are removing the definition of person in both parts because the term is no longer used in 7 CFR part 331 and 9 CFR part 121. In addition, we are removing the definition of responsible facility official from both parts and adding responsible official in its place. We are removing the definition of responsible facility official because the term is no longer used in 7 CFR part 331 and 9 CFR part 121. The term responsible facility official (RFO) was initially adopted by CDC for its select agent program (42 CFR part 72) and it is too limited in scope for our purposes. Specifically, the term only refers to transfers (rather than possession, use, and transfers) and dictates who should be the RFO (a safety officer, a senior management official, or both). We believe that these individuals may not always be the appropriate individual to ensure compliance with these regulations.

Therefore, we use the term responsible official in 7 CFR part 331 and 9 CFR part 121. We define responsible official as "the individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this part." We believe that this definition is broad enough to allow entities to designate the

appropriate individual to be the responsible official, and it places the responsibility of selecting the appropriate individual on the entity, rather than on APHIS.

To be consistent with CDC, we are also removing the definition of facility in both parts and adding entity in its place. We define entity as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."

Furthermore, in 9 CFR part 121, we are revising the definition of overlap agent or toxin to reflect changes made to the definitions of biological agent and toxin in the September 2002 technical amendment noted previously and changes made to the list in this rule. Thus, overlap agent or toxin is defined as "any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) or toxin that poses a risk to both human and animal health and that is listed in § 121.3(b)."

In this interim rule, we define the terms Administrator, APHIS, Attorney General, CDC, diagnostic laboratory, import, interstate, permit, State, United States, and USDA in both 7 CFR 331.1 and 9 CFR 121.1. Administrator is defined as "the Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator." APHIS is defined as "the Animal and Plant Health Inspection Service of the United States Department of Agriculture." Attorney General is defined as "the Attorney General of the United States or any person authorized to act for the Attorney General." CDC is defined as "the Centers for Disease Control and Prevention of the United States Department of Health and Human Services." Diagnostic laboratory is defined as "a laboratory facility that receives specimens for the purpose of determining identities of pests, pathogens, contaminants, or causes of disease." USDA is defined as "the United States Department of Agriculture."

To clarify the transfer provisions in the regulations, we define permit as "written authorization by the Administrator to import or move interstate biological agents or toxins, under conditions prescribed by the Administrator." Import means "to move into, or the act of movement into, the territorial limits of the United States," while interstate means "from one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States." In addition, we define State as "any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States." Finally, the term United States means "all of the States."

In 7 CFR 331.1, we also define PPQ and specimen. PPQ is defined as "the Plant Protection and Quarantine Programs of the Animal and Plant Health Inspection Service." Specimen is defined as "a sample of material collected for use in testing, such as plant tissues (e.g., stems, seeds, flowers, pollen, leaves, roots, fruits, tubers, tissue cultures, protoplasts), soil, water, swabs, cultures, and suspensions."

In 9 CFR 121.1, we also define clinical laboratory, proficiency testing, and specimen to clarify the exemption provisions for clinical or diagnostic laboratories in that part. Clinical laboratory is defined as "a laboratory facility that receives patients and collects specimens for processing or shipping to another laboratory," while proficiency testing is defined as "a sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated for acceptance." Finally, specimen is defined as "a sample of material collected for

use in testing, such as tissues, gastrointestinal contents, feces, bodily fluids (blood, serum, etc.), soil, water, feed or feed ingredients, swabs, cultures, and suspensions."

Purpose and Scope

To facilitate understanding of the regulations, both 7 CFR 331.2 and 9 CFR 121.2 discuss the purpose and scope of the regulations. Specifically, 7 CFR 331.2(a) states that part 331 sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to plant health or plant products, while 9 CFR 121.2(a) states that part 121 sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to both human and animal health, or to animal health or animal products. Both 7 CFR 331.2(a) and 9 CFR 121.2(a) note that the purpose of the regulations is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose.

In 7 CFR 331.2(b) and 9 CFR 121.2(b), we further provide that any individual or entity that possesses, uses, or transfers any listed agent or toxin must register in accordance with §§ 331.6 and 121.7, respectively. In order for an entity to register, each entity must designate an individual who has the authority and control to ensure compliance with the regulations to be the responsible official. It is the responsible official who must complete and submit the registration application package to APHIS or, for overlap agents or toxins, to APHIS or CDC. As part of registration, the responsible official, the entity, and, where applicable, the individual who owns or controls such entity will be subject to a security risk assessment by the Attorney General.

Finally, 7 CFR 331.2(c) and 9 CFR 121.2(c) state that the responsible official is responsible for ensuring compliance with the safety procedures in the regulations, including

implementing the Biocontainment and Security Plan (7 CFR 331.11) or the Biosafety and Security Plan (9 CFR 121.12); providing the proper training to individuals that handle or use listed agents or toxins; and providing proper laboratory facilities to contain and dispose of such agents or toxins. In addition, the responsible official is responsible for ensuring compliance with the safeguard and security measures in the regulations, including restricting access to only those individuals who have a legitimate need to handle or use agents or toxins and who have been approved to handle or use such agents or toxins, and transferring listed agents or toxins only to registered individuals or entities.

List of Biological Agents and Toxins

In our August 2002 interim rule, we established the initial lists of biological agents and toxins required under section 212(a)(1) of the Act. In this interim rule, we are amending the lists of biological agents and toxins in both 7 CFR 331.3 and 9 CFR 121.3.

We have made several changes to 7 CFR 331.3. In 7 CFR 331.3(a), we have amended the entry for Ralstonia solanacearum, race 3. A comment submitted in response to our August 2002 interim rule reported that race 3 strains are common in the United States and should not be listed; however, race 3, biovar 2 strains are not common in the United States and would pose a severe threat to plant health or plant products if introduced. We agree and have amended the entry for Ralstonia solanacearum to specify race 3, biovar 2.

In addition, we have added several provisions that limit the applicability of the regulations in part 331. First, in 7 CFR 331.3(b) we provide that any biological agent or toxin listed in that section that is in its naturally occurring environment will not be subject to the requirements of part 331, provided that the biological agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source. We have

included this provision because we believe that it would be impractical to regulate a biological agent or toxin that is in its naturally occurring environment. Listed agents or toxins could be found in castor beans or corn going to market, for example, and it would be impractical to apply these regulations in such cases.

Second, in 7 CFR 331.3(c) we provide that biological agents or toxins that meet certain criteria do not have the potential to pose a severe threat to plant health or to plant products. Thus, an individual or entity that only possesses, uses, or transfers an agent or toxin that meets any of the following criteria will not be subject to the requirements of this part: (1) Nonviable agents that are, bear, or contain listed agents or toxins; or (2) genetic elements or subunits of listed agents or toxins, if the genetic elements or subunits are not capable of causing disease.

We have also made several changes to the list in 9 CFR 121.3 to be consistent with CDC and to reflect changes in scientific nomenclature. In June 2002, CDC convened an interagency working group to review its list of 36 select agents, some of which are the overlap agents that are listed in our regulations, and develop recommendations regarding possible changes to that list. Because that process was in its initial stages at the time we published the August 2002 interim rule that established the list of biological agents and toxins, the list of overlap agents and toxins reflected the select agent list promulgated by CDC in October 1996. The interagency working group has since submitted its recommendations to CDC.

Based on the interagency working group's recommendations, we have removed aflatoxin from the list of overlap agents and toxins in § 121.3(b), and we have moved Nipah virus from the animal agent and toxin list to the overlap agent and toxin list. In addition, we have added Botulinum neurotoxin producing species of Clostridium to the overlap agent and toxin list.

Due to changes in scientific nomenclature, in 9 CFR 121.3(b) we have replaced the entry for equine morbillivirus (Hendra virus) with Hendra virus; replaced Burkholderia (Pseudomonas) mallei with Burkholderia mallei; replaced Burkholderia (Pseudomonas) pseudomallei with Burkholderia pseudomallei; and replaced Botulinum toxin with Botulinum neurotoxins.

In 9 CFR 121.3(c), we have adopted CDC's provisions regarding genetic elements, recombinant nucleic acids, and recombinant organisms to be consistent with CDC's list of overlap agents and toxins.

To clarify that we are regulating the agent that causes disease rather than the disease itself and to be consistent with CDC's approach, in 9 CFR 121.3(d) we have replaced the entry for avian influenza (highly pathogenic) with avian influenza virus (highly pathogenic); replaced African swine fever with African swine fever virus; replaced classical swine fever with classical swine fever virus; replaced malignant catarrhal fever with malignant catarrhal fever virus (exotic); replaced Peste des petits ruminants with Peste des petits ruminants virus; replaced sheep pox with sheep pox virus; and replaced vesicular stomatitis (exotic) with vesicular stomatitis virus (exotic).

In addition, in 9 CFR 121.3(d) we have replaced the entry for Newcastle disease virus (exotic) with Newcastle disease virus (VVND) to make it clear that we are regulating only velogenic strains.

Moreover, in 9 CFR 121.3 we have added several provisions that limit the applicability of the regulations in part 121. First, in 9 CFR 121.3(e) we provide that any biological agent or toxin listed in that section that is in its naturally occurring environment will not be subject to the requirements of part 121, provided that the biological agent or toxin has not been intentionally

introduced, cultivated, collected, or otherwise extracted from its natural source. We have included this provision because we believe that it would be impractical to regulate a biological agent or toxin that is in its naturally occurring environment. Listed agents or toxins could be found in cattle or infected humans, for example, and it would be impractical to apply these regulations in such cases.

Second, in 9 CFR 121.3(f) we provide that biological agents or toxins that meet certain criteria do not have the potential to pose a severe threat to both human and animal health, or to animal health or animal products. Therefore, an individual or entity possessing, using, or transferring an agent or toxin that meets any of the following criteria will not be subject to the requirements of part 121:

(1) Nonviable agents or fixed tissues that are, bear, or contain agents or toxins listed in § 121.3. However, we note that the importation and interstate movement of these nonviable agents and fixed tissues are still subject to the permit requirements under 9 CFR part 122; or

(2) Genetic elements or subunits of animal agents or toxins listed in § 121.3(d), if the genetic elements or subunits are not capable of causing disease. However, we note that the importation and interstate movement of these genetic elements or subunits of listed agents or toxins are still subject to the permit requirements under 9 CFR part 122; or

(3) Overlap toxins under the control of a principal investigator (or equivalent), if the total aggregate amount does not, at any time, exceed the following amounts: 0.5 mg of Botulinum neurotoxins (types A-G), 100 mg of Clostridium perfringens epsilon toxin, 100 mg of Shigatoxin, 5 mg of Staphylococcal enterotoxins, and 1,000 mg of T-2 toxin.

Finally, in 9 CFR 121.3(g) we have established a procedure by which an individual or entity may request a determination by the Administrator that an attenuated strain of a biological

agent does not pose a severe threat to both human and animal health, or to animal health or animal products. This provision is necessary because some attenuated strains of a biological agent may not pose a severe threat to both human and animal health, or to animal health or animal products. Therefore, by definition, such attenuated strains would be excluded from the list of biological agents or toxins in § 121.3.

Accordingly, 9 CFR 121.3(h) provides that an individual or entity may request review by the Administrator to determine whether or not a specific attenuated strain poses a severe threat to both human and animal health, or to animal health or animal products. For overlap agents, an individual or entity may request review by APHIS or CDC. If APHIS or CDC determines that a specific attenuated strain does not pose a severe threat to human and animal health, or to animal health or animal products, and the individual or entity in possession of that particular attenuated strain will not be subject to the requirements of part 121. We note, however, that this determination will be limited to the specific attenuated strain and to the specific activities involving that attenuated strain.

APHIS or CDC will notify the applicant and publish a notice in the Federal Register if it is determined that a specific attenuated strain does not pose a severe threat to human and animal health, to animal health, or to animal products, the individual or entity in possession of that particular attenuated strain will not be subject to the requirements of part 121. Under 9 CFR 121.3(h)(4), an individual or entity may request reconsideration of an adverse decision in writing to the Administrator.

Section 212(a)(2) of the Act requires that the lists of biological agents and toxins be reviewed and republished biennially, or more often as needed, and revised as necessary. In addition, the Act requires that, when determining whether to include an agent or toxin, the

Secretary shall consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups. To accomplish this, we may hold public meetings to provide the opportunity for Federal departments and agencies and scientific experts to comment on the lists in 7 CFR 331.3 and 9 CFR 121.3.

Exemptions

Section 212(g)(1) of the Act explicitly sets forth the exemptions for overlap agents and toxins. The exemptions for overlap agents and toxins in 9 CFR 121.4 match the provisions in the Act. We set forth similar provisions for exemptions for plant agents and toxins in 7 CFR 331.4 and animal agents and toxins in 9 CFR 121.5.

In accordance with section 212(g)(1)(B) of the Act, 9 CFR 121.4(a) provides that clinical or diagnostic laboratories and other entities possessing, using, or transferring overlap agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of part 121, provided that the identification of such agents or toxins is immediately reported to the APHIS or CDC, and to other appropriate authorities when required by Federal, State, or local law; and, within 7 days after identification, such agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to APHIS or CDC. We further provide that a copy of the completed form must be maintained for 3 years.

Based on information provided by CDC and APHIS' National Veterinary Services Laboratories (NVSL), and taking into consideration the threat posed by listed agents and toxins, we believe that 7 days will provide ample time after identification to inactivate the agent or toxin, or to make transfer arrangements and to transfer the agent or toxin.

To be consistent with the exemptions for overlap agents and toxins, in 7 CFR 331.4(a) and 9 CFR 121.5(a) we have adopted this exemption for diagnostic laboratories (the term clinical

laboratories is not applicable to the plant-related regulations in 7 CFR part 331 or the animal-related regulations in 9 CFR part 121). We note, however, that diagnostic laboratories and other entities will still be required to obtain a permit under 7 CFR part 330 and 9 CFR part 122 to import and move interstate any listed agent or toxin.

In 7 CFR 331.4(a), 9 CFR 121.4(a), and 9 CFR 121.5(a), we further provide that, during agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. For example, during an outbreak, we may allow biweekly reporting of identifications of a specific agent. In such cases, we will inform the diagnostic laboratories or other entities of this temporary change to the notification requirements.

In 9 CFR part 121, we also provide an exemption for clinical or diagnostic laboratories and other entities conducting proficiency testing. Specifically, in 9 CFR 121.4(b) we provide that clinical or diagnostic laboratories and other entities possessing, using, or transferring overlap agents or toxins that are contained in specimens presented for proficiency testing will be exempt from the requirements of part 121, provided that the identification of such agents or toxins, and their derivatives, is reported to the APHIS or CDC and to other appropriate authorities when required by Federal, State, or local law; and within 90 days of receipt of the agents or toxins, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to APHIS or CDC. We further provide that a copy of the completed form must be maintained for 3 years.

Paragraph (a) of 9 CFR 121.5 contains the same exemption provision for animal agents or toxins that are contained in specimens presented for proficiency testing. Based on information provided by NVSL, which conducts such proficiency testing, we believe that 90 days will provide ample time to run the necessary tests for any listed agent or toxin.

We wish to emphasize that a clinical or diagnostic laboratory, or other entity, will be exempt only if it satisfies the specific requirements of these exemptions. Clinical or diagnostic laboratories and other entities must register in accordance with the regulations if they wish to maintain a viable agent or active toxin as a positive control. This is consistent with the "fundamental premise of the [Act]—that all those who maintain possession of a [listed biological agent or toxin] must register and be subject to appropriate security and safety requirements." (H.R. Conf. Rep. No. 107-481, at 122 (2002)).

Pursuant to section 212(g)(1)(C) of the Act, the regulations in 9 CFR part 121 provide exemptions for products that are, bear, or contain agents or toxins that have been cleared, approved, licensed, or registered under certain Federal laws. Generally, we believe that it is unnecessary to impose additional regulation on products that have been cleared, approved, licensed, or registered pursuant to certain Federal laws because these laws already provide adequate safeguards. However, it is possible there will be some instances when existing regulation under Federal law is inadequate. In those instances, the regulations provide that the Administrator may impose additional regulation if he or she determines that it is necessary to protect animal or plant health, and animal or plant products.

Accordingly, for overlap agents or toxins and animal agents or toxins, 9 CFR part 121 (§§ 121.4(c) and 121.5(e), respectively) provides that, unless the Administrator by order determines that additional regulation of a specific product is necessary to protect animal health, or animal products, an individual or entity possessing, using, or transferring products that are, bear, or contain agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151-159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 et seq.).

In addition, in 9 CFR 121.4(d) we provide that an individual or entity possessing, using, or transferring investigational products that are, bear, or contain overlap agents or toxins may be exempt from the requirements of this part if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal health or animal products. An individual or entity possessing, using, or transferring such investigational products may apply for an exemption from the requirements of this part by submitting APHIS Form 2042 to APHIS or CDC. Given the time sensitivity of investigational or clinical trials, the Administrator shall make a determination regarding an exemption within 14 days after receipt of the application and notification that the investigation has been authorized under a Federal law.

We have added a similar provision for experimental products in 9 CFR 121.5(f). However, because it is not required by the Act, in § 121.5(f) we did not stipulate that the Administrator will make a determination regarding an exemption within 14 days after receipt of the application and notification that the investigation has been authorized under a Federal law. We did not include this provision in order to give the Administrator the discretion to take longer than 14 days to make a determination, when necessary. However, we expect that the Administrator will make determinations regarding such exemptions in a timely manner.

Furthermore, in 9 CFR 121.5(c) we provide that an individual or entity receiving diagnostic reagents and vaccines that are, bear, or contain listed agents or toxins, also known as high consequence livestock pathogens or toxins, that are produced at USDA diagnostic facilities

will be exempt from the requirements of part 121. These diagnostic reagents and vaccines are products that would be cleared, approved, licensed, or registered pursuant to the Virus-Serum-Toxin Act (21 U.S.C. 151-159), but for the fact that they are produced by USDA.

In accordance with section 212(g)(1)(D) of the Act, 9 CFR 121.4(e) provides that the Administrator may exempt an individual or entity from the requirements of the regulations, in whole or in part, for 30 days if it is necessary to respond to a domestic or foreign agricultural emergency involving an overlap agent or toxin. The Administrator may extend the exemption once for an additional 30 days, as deemed necessary.

In 9 CFR 121.4(f), we set forth a similar provision for public health emergencies. Specifically, § 121.4(f) provides that, upon request of the Secretary of Health and Human Services, the Administrator may exempt an individual or entity from the requirements of the regulations, in whole or in part, for 30 days if the Secretary of Health and Human Services has granted an exemption for a public health emergency involving an overlap agent or toxin. The Administrator may extend the exemption once for an additional 30 days, as deemed necessary.

Finally, section 212(g)(2) of the Act provides that the Secretary may grant exemptions from the applicability of the regulations if the Secretary determines that such exemptions are consistent with protecting animal or plant health and animal or plant products. This general exemption authority affords the Secretary more discretion to exempt plant and animal agents and toxins than overlap agents and toxins, since the Act specifically sets forth the exemptions for overlap agents and toxins.

Accordingly, 7 CFR 331.4(b) and 9 CFR 121.5(f) indicate that the Administrator may grant exemptions from the requirements of these parts upon a showing of good cause and a determination that it is consistent with protecting animal or plant health and animal or plant

products. For example, such exemptions may be granted for agricultural emergencies involving plant or animal agents or toxins. An individual or entity may request in writing an exemption from the requirements of the regulations.

Registration Requirements and Procedures

In accordance with section 212(d) of the Act, 7 CFR 331.5(a) and 9 CFR 121.6(a) require that, unless exempted under those parts, an individual or entity possessing, using, or transferring listed agents or toxins must register with APHIS. Section 121.6(a) of 9 CFR part 121 further requires that an individual or entity possessing, using, or transferring overlap agents or toxins must register with APHIS or CDC.

We note that Congress expected that most registrants would be public and private entities, rather than individuals. (H.R. Conf. Rep. No. 107-481, at 125 (2002)). Thus, 7 CFR 331.5(b) and 9 CFR 121.6(b) indicate that, to apply for a certificate of registration, each entity must designate an individual to be the responsible official. The responsible official must have the authority and control to ensure compliance with the regulations. The responsible official must complete and sign the registration application package, and will be the individual contacted by APHIS or CDC if any questions arise concerning the application or subsequent compliance. As part of registration, the responsible official and the entity will be subject to a security risk assessment by the Attorney General.

While most registrants are likely to be entities, both 7 CFR 331.5(b) and 9 CFR 121.6(b) provide that, in the event that an individual applies for and is granted a certificate of registration, we will consider the individual to be the responsible official.

We wish to emphasize that it is the entity's responsibility to designate the appropriate individual to be the responsible official (i.e., an individual who has the authority and control to

ensure compliance with the regulations). To satisfy this requirement, a university may choose to designate the Dean of Agriculture to be the responsible official rather than the biosafety officer because the Dean of Agriculture may have better oversight and authority to ensure compliance with the regulations.

Furthermore, we note that a certificate of registration will apply to only one general physical location (e.g., a building or complex of buildings at a single mailing address). If an entity has more than one general physical location, then the entity must register each location and must designate an individual to be the responsible official for each location.

Although not contemplated by the Act, we recognize that there may be times when the responsible official is unavailable. Since some functions may only be performed by the responsible official (i.e., transfers), this may disrupt research or other approved activities. Therefore, in 7 CFR 331.5(c) and 9 CFR 121.6(c), we provide that an entity may designate one or more individuals to be an alternate responsible official, who may act for the responsible official when that individual is unavailable. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official. These individuals will also be subject to a security risk assessment by the Attorney General as part of registration.

To apply for a certificate of registration, 7 CFR 331.8(a) and 9 CFR 121.9(a) provide that the responsible official must submit all of the information and documentation required in the registration application package to APHIS, including the name, source, and characterization data for each agent or toxin to be registered, as required by section 212(d)(2) of the Act. For overlap agents or toxins, the responsible official must submit all of the information and documentation required in the registration package to either APHIS or CDC. The responsible official must

submit the registration application package to APHIS in cases where he/she is seeking registration for either plant and animal agents or toxins, and overlap agents or toxins.

In 7 CFR 331.6(b) and 9 CFR 121.7(b), we provide that APHIS may issue a certificate of registration upon:

(1) Approval of the responsible official; the alternate responsible official, where applicable; the entity; and, where applicable, the individual who owns or controls the entity following a security risk assessment by the Attorney General. As provided for by the Act, we may waive the security risk assessment of the entity and the individual who owns or controls such entity for Federal, State, or local governmental agencies;

(2) Approval of the containment and security of the entity (7 CFR 331.6) or approval of the biosafety, containment, and security of the entity (9 CFR 121.7). For plant-related agents or toxins, the entity's containment and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. Similarly, for overlap and animal agents or toxins, the entity's biosafety, containment, and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS will review the Biocontainment and Security Plan or the Biosafety and Security Plan, as applicable, and may inspect and evaluate the premises and records to determine compliance with the regulations and the biosafety and/or containment and security requirements. For overlap agents and toxins, APHIS or CDC will review the Biosafety and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the biosafety and/or containment and security requirements; and

(3) A determination by the Administrator that the individual or entity seeking to register has a lawful purpose to possess, use, or transfer such agents or toxins.

Furthermore, 9 CFR 121.7(c) provides that APHIS and CDC will review applications for registration and amendments to a certificate of registration for overlap agents or toxins, and a certificate of registration or amendment to a certificate of registration will only be issued if APHIS and CDC concur.

As indicated in 7 CFR 331.6(c) and 9 CFR 121.7(d), a certificate of registration will be valid for only specific agents or toxins, and specific activities and locations. A certificate of registration may cover more than one listed agent or toxin, and it may be amended to cover additional listed agents or toxins. A responsible official may request an amendment to a certificate of registration by submitting the relevant pages from the registration application package to the agency that issued the certificate of registration, either APHIS or CDC.

Furthermore, under 7 CFR 331.6(d) and 9 CFR 121.7(e), a certificate of registration may be amended to reflect changed circumstances (e.g., replacement of the responsible official, changes in ownership or control of the entity, changes in the activities involving the agent or toxin). The responsible official must immediately notify the agency that issued the certificate of registration, either APHIS or CDC, of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration. We note that replacement of the responsible official or change in ownership or control of an entity will require a security risk assessment for the new individual(s) who owns or controls the entity.

There may be instances where a responsible official wishes to discontinue possessing, using, or transferring one or more agents or toxins for which they are registered. In those instances, 7 CFR 331.5(e) and 9 CFR 121.6(f) state that the responsible official may inactivate the agent or toxin or he/she may transfer the agent or toxin to a registered individuals or entities. The responsible official must notify APHIS or, for overlap agents, APHIS or CDC, 5 business

days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. APHIS or CDC will notify the responsible official if we wish to observe the inactivation of the agents or toxins.

Finally, 7 CFR 331.6(f) and 9 CFR 121.7(g) indicate that a certificate of registration will be valid for a maximum of 3 years. To minimize the administrative burden associated with this new registration program, initially we will assign expiration dates ranging from 24 to 36 months to stagger the dates for renewing registration. Upon renewal, we expect that all certificates of registration will be valid for 3 years.

Denial, Revocation, and Suspension of Registration

Section 212(e)(6)(A) of the Act provides that an individual who seeks to register shall be subject to a database check by the Attorney General. Section 212(e)(6)(B) goes on to provide that other persons (i.e., entities) shall be subject to a database check by the Attorney General, and, where applicable, the individual who owns or control such person (i.e., entity) shall be subject to a database check by the Attorney General.

Pursuant to section 212(e)(3) of the Act, upon receipt of the names and identifying information of those seeking to register, the Attorney General will use criminal, immigration, national security, and other electronic databases for the purpose of identifying whether the individuals are within any of the categories described in 18 U.S.C. 175b (relating to restricted persons). According to 18 U.S.C. 175b, "the term 'restricted person' means an individual who:

(A) Is under indictment for a crime punishable for a term exceeding 1 year;

(B) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

(C) Is a fugitive from justice;

(D) Is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(E) Is an alien illegally or unlawfully in the United States;

(F) Has been adjudicated as a mental defective or has been committed to any mental institution;

(G) Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or

(H) Has been discharged from the Armed Services of the United States under "dishonorable conditions."

Section 212(e)(3) of the Act further provides that the Attorney General will use criminal, immigration, national security, and other electronic databases for the sole purpose of identifying whether the individuals are reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5); knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801.

Accordingly, in 7 CFR 331.7(a) and 9 CFR 121.8(a) we provide that APHIS may deny an application for registration or revoke registration if the Attorney General identifies the individual as within any of the categories described in the previous paragraphs.

With regard to overlap agents or toxins, 9 CFR 121.8(b) provides that APHIS or CDC will deny an application for registration or revoke registration if the Attorney General identifies the individual as a "restricted person" as described in 18 U.S.C. 175b. APHIS or CDC may deny an application for registration or revoke registration if the Attorney General identifies the individual as within any of the remaining categories described above.

Furthermore, in keeping with the safety and security requirements of the Act, in 7 CFR 331.7(a) and 9 CFR 121.8(a), we provide that APHIS may deny an application for registration or revoke registration if the responsible official does not have a lawful purpose to possess, use, or transfer listed agents or toxins; the responsible official is an individual who handles or uses listed agents or toxins and he/she does not have the necessary training or skills to handle such agents or toxins; the entity does not meet the biosafety and/or containment and security requirements prescribed by the Administrator; there are egregious or repeated violations of the biosafety, containment, or security requirements; or the Administrator determines that such action is necessary to protect animal or plant health, and animal or plant products.

We may summarily revoke or suspend registration for any of the reasons set forth in 7 CFR 331.7(a) and in paragraphs (a) and (b) of 9 CFR 121.8. In accordance with 7 CFR 331.7(c) and 9 CFR 121.8(d), we will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended. For overlap agents or toxins, APHIS or CDC will provide the necessary notification.

Finally, both parts provide that denial of an application for registration, revocation of registration, and suspension of registration may be appealed under §§ 331.16 and 121.17, respectively.

Responsibilities of the Responsible Official

To facilitate compliance with the regulations, 7 CFR 331.9 and 9 CFR 121.10 both set out the responsibilities of the responsible official. Specifically, the regulations indicate the responsible official is responsible for:

- Developing and implementing a Biocontainment and Security Plan or a Biosafety and Security Plan, as applicable;
- Allowing only approved individuals within the entity to have access to listed agents or toxins;
- Providing appropriate training in biosafety and/or containment and security procedures for all personnel;
- Transferring agents or toxins only to registered individuals or entities;
- Ensuring that all visitors are informed of and follow the entity's security requirements and procedures;
- Notifying APHIS or, for overlap agents, APHIS or CDC, of changes in circumstances;
- Providing timely notice of any theft, loss, or release of a biological agent or toxin; and
- Maintaining detailed records of information necessary to give a complete accounting of all of the entity's activities related to agents or toxins.

In addition, both parts provide that the responsible official for a diagnostic laboratory or other entity possessing, using, or transferring listed agents or toxins that are contained in specimens presented for diagnosis must immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law. Furthermore, both parts provide that the Administrator may require less frequent reporting during agricultural emergencies or outbreaks, or in endemic areas. We are adopting

these reporting requirements because this information will help us to identify outbreaks and to monitor activities related to listed agents and toxins.

Finally, to be consistent with CDC, we have adopted the CDC's approach on experiments involving recombinant DNA. We believe this provision will address concerns about laboratory manipulation of microbes that alter their characteristics (e.g., increased virulence, pathogenicity, or host range; alter mode of transmission or route of exposure) and increase the risks to human, animal, or plant health.

Accordingly, in 9 CFR 121.10(c) we provide that a responsible official must ensure that the following experiments are not conducted unless approved by the Administrator, after consultation with experts:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a pathogenic trait or drug resistance trait to biological agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture; and

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD_{50}<100 ng/kg body weight.

In addition, we request comments concerning what additional experiments, regardless if regulated under these regulations, might warrant similar scrutiny in the interest of safety. In particular, we request comments addressing issues concerning experiments with biological agents that could possibly increase their virulence or pathogenicity, change their natural mode of transmission, route of exposure, or host range in ways adverse to human, animal, or plant health; or result in the deliberate transfer a drug resistant trait or a toxin-producing capability to a microorganism by means that do not involve recombinant DNA techniques. We also request

comments regarding the form oversight should take; for example, the rule could require that, whenever laboratory manipulation of a microorganism increases its risk profile significantly, whether intentionally or inadvertently, the responsible official report such to the Administrator and discontinue work with the modified organism until the Administrator has made recommendations regarding appropriate safety practices.

Restricting Access to Biological Agents and Toxins

Section 212(e)(1) of the Act provides that the Secretary shall establish appropriate safeguard and security requirements for persons possessing, using, or transferring biological agents or toxins commensurate with the risk such agent poses to animal and plant health, and animal and plant products (including the risk of use in domestic or international terrorism). Section 212(e)(2)(A) goes on to state that the regulations must include provisions to ensure that the registered person provides access to listed agents and toxins to only those individuals whom the registered person has determined have a legitimate need to handle or use such agents or toxins. In addition, section 212(b)(1)(A) requires that the Secretary establish and enforce safety procedures for agents and toxins, including measures to ensure proper training and appropriate skills to handle such agents and toxins.

Accordingly, 7 CFR 331.10(a) and 9 CFR 121.11(a) provide that an individual may not have access to biological agents or toxins listed in §§ 331.3 and 121.3, respectively, unless approved by APHIS or, for overlap agents, APHIS or CDC. Both parts require the responsible official to ensure that only approved individuals within the entity have access to listed agents or toxins. In addition, the responsible official must request such access for only those individuals who have a legitimate need to handle or use listed agents or toxins, and who have the appropriate training and skills to handle such agents or toxins.

We recognize that a responsible official may want to minimize the number of individuals who require access approval. Accordingly, we reiterate that such approval is necessary only for those individuals who have a legitimate need to handle or use agents or toxins, and who have the appropriate training and skills to handle such agents or toxins. For those individuals who do not have a legitimate need to handle or use agents or toxins, or who do not have the appropriate training and skills to handle agents or toxins (e.g., visitors, janitorial and maintenance staff, and contractors), a responsible official may restrict access to agents or toxins by requiring that such individuals be escorted at all times by an individual with access approval from APHIS or CDC. If a responsible official adopts such a practice, it should be contained in the Biocontainment and Security Plan or the Biosafety and Security Plan, as applicable.

To ensure that individuals who handle or use listed agents or toxins have the appropriate training and skills, 7 CFR 331.10(c) requires that the responsible official must provide appropriate training in containment and security procedures to all individuals with access to agents and toxins in accordance with 7 CFR 331.12. Similarly, 9 CFR 121.11(c) requires that the responsible official must provide appropriate training in biosafety and/or containment and security procedures to all individuals with access to agents and toxins in accordance with 9 CFR 121.13.

Furthermore, the responsible official must provide APHIS with information about the individual's training and skills, such as a curriculum vitae for principal investigators and researchers, and a description of training completed by support personnel (7 CFR 331.10(e) and 9 CFR 121.11(e)).

In order to obtain access approval for an individual, section 212(e)(2)(B) of the Act requires that the responsible official submit the names and identifying information for those

individuals deemed to have a legitimate need to handle or use listed agents or toxins to the Secretary and the Attorney General, promptly after determining the individuals need access, and periodically thereafter, not less frequently than once every 5 years. We note that the screening of employees working with agents or toxins is the primary responsibility of the responsible official, not the individual employee. (H.R. Conf. Rep. No. 107-481, at 125 (2002)).

Both 7 CFR 331.10(d) and 9 CFR 121.11(d) indicate that, for each individual identified by the responsible official as having a legitimate need to handle or use listed agents or toxins, the responsible official must submit that individual's name and identifying information to APHIS and the Attorney General. Paragraph (d) of 9 CFR 121.11 further provides that, for overlap agents, the responsible official must submit this information to either APHIS or CDC and the Attorney General.

Pursuant to section 212(e)(3) of the Act, upon receipt of the names and identifying information, the Attorney General will use criminal, immigration, national security, and other electronic databases for the purpose of identifying whether the individuals are within any of the categories described in 18 U.S.C. 175b (relating to restricted persons). Section 212(e)(3) of the Act further provides that the Attorney General will use criminal, immigration, national security, and other electronic databases for the purpose of identifying whether the individuals are reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5); knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801.

In 7 CFR 331.10(h) and 9 CFR 121.11(h), we provide that we may deny or limit access of an individual to listed agents or toxins if the Attorney General identifies the individual as within any of the categories described in the previous paragraph. This is consistent with the requirements in section 212(e)(2)(C)(i) of the Act.

With regard to overlap agents or toxins, 9 CFR 121.11(i) provides that APHIS or CDC will deny an individual access to overlap agents or toxins if the Attorney General identifies the individual as a "restricted person" as described in 18 U.S.C. 175b. APHIS or CDC may deny or limit access of an individual if the Attorney General identifies the individual as within any of the remaining categories described above.

Furthermore, in keeping with the safety and security requirements of the Act, both 7 CFR 331.10(h) and 9 CFR 121.11(h) provide that we may deny or limit access if the individual does not have a legitimate need to handle listed agents or toxins; the individual does not have the necessary training or skills to handle listed agents or toxins; or the Administrator determines that such action is necessary to protect animal or plant health or animal or plant products.

The Administrator will determine what constitutes limited access on a case-by-case basis. The determination will take into consideration all the facts at hand and be commensurate with the risks posed by the agent or toxin. Generally, we expect that an individual granted limited access will only be allowed to handle or use an agent or toxin under the direct supervision of an approved individual.

Section 212(e)(3)(C) of the Act provides that the Attorney General will notify the Secretary whether the individual is within any of the categories discussed previously. Then the Secretary will notify the responsible official if an individual is granted or denied access to listed agents or toxins (section 212(e)(4)).

Accordingly, both 7 CFR 331.10(g) and 9 CFR 121.11(g) provide that we will notify the responsible official if an individual is granted full or limited access, or denied access, to biological agents or toxins, and we will notify the individual if he/she is denied access or granted only limited access to such agents or toxins. Paragraph (g) of 9 CFR 121.11 further provides that, for overlap agents or toxins, APHIS or CDC will provide the necessary notification.

Pursuant to section 212(e)(5) of the Act, 7 CFR 331.10(f) and 9 CFR 121.11(f) indicate that we may expedite the access approval process for individuals upon request by the responsible official and a showing of good cause, such as public health or agricultural emergencies, national security, impending expiration of a research grant, or a short-term visit by a prominent researcher. We note, however, that the Act specifically provides that expedited review is not available for individuals or entities seeking to register (section 212(e)(6)).

Both 7 CFR 331.10(j) and 9 CFR 121.11(k) provide that access approval for individuals is valid for 5 years and, thereafter, the responsible official shall request access approval every 5 years for as long as the individual needs access to such agents or toxins. This is consistent with the requirements of the Act.

In 7 CFR 331.10(k) and 9 CFR 121.11(l), we further provide that the responsible official must immediately notify APHIS or, for overlap agents or toxins, APHIS or CDC, when an individual's access to listed agents or toxins is terminated by the entity and the reasons therefore. We believe this information will be relevant to any subsequent determinations to allow that individual access to listed agents or toxins.

Section 212(e)(7)(A)(i) of the Act requires that the regulations provide for an opportunity for review by the Secretary, when requested by the individual involved, of a determination to deny that individual access to listed agents or toxins. Thus, 7 CFR 331.10(i) and 9 CFR

121.11(j) provide that an individual may appeal the Administrator's decision to deny or limit access to biological agents or toxins, in accordance with §§ 331.16 and 121.17, respectively.

Biocontainment and Security Plan/Biosafety and Security Plan

Sections 212(b) and (c) of the Act require that the Secretary establish and enforce safety procedures for listed agents and toxins, including measures to ensure proper training and appropriate skills to handle agents and toxins, and proper laboratory facilities to contain and dispose of agents and toxins. In addition, sections 212(b) and (c) of the Act require that the Secretary establish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose. Pursuant to section 212(e)(1), the safeguard and security requirements must be commensurate with the risk posed by the agent or toxin.

Because different agents and toxins pose differing degrees of risk, depending on factors such as their escape potential and availability of a suitable habitat (for plant-related agents) and transmission and effect of exposure to the agent or toxin (for overlap and animal agents or toxins), we believe that it would be counterproductive to attempt to prepare a detailed list of prescriptive requirements for entities (i.e., a "one size fits all" design standard). Rather, we have prepared a brief set of performance standards that we will consider to the degree to which they are appropriate to the risks presented by a particular agent or toxin, given its intended use and the location of the entity.

Accordingly, 7 CFR 331.11 requires that, as a condition of registration, an individual or entity must develop and implement a Biocontainment and Security Plan. Similarly, 9 CFR 121.12 requires that, as a condition of registration, an individual or entity must develop and implement a Biosafety and Security Plan. The titles and provisions of the plans are different

because the agents listed under 7 CFR 331.3 do not pose a severe threat to human health and, therefore, it is unnecessary to require that the plant-related plan address personnel safety and health.

In 7 CFR 331.11, we provide that the plan must contain sufficient information and documentation to describe the containment procedures and the security systems and procedures. The plan's containment and security provisions must be commensurate with the risk posed by the agent or toxin, given its intended use.

Similarly, in 9 CFR 121.12 we provide that the plan must contain sufficient information and documentation to describe the biosafety and containment procedures, and the security systems and procedures. The plan's biosafety, containment, and security provisions must be commensurate with the risk posed by the agent or toxin, given its intended use.

Pursuant to section 212(e)(9) of the Act, we will provide technical assistance and guidance upon request to help individuals and entities develop their plans.

In 7 CFR 331.11(a)(1), we provide that the plan's containment procedures must be sufficient to contain the agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards) while in 9 CFR 121.12(a)(1) we provide that the plan's biosafety and containment procedures must be sufficient to contain the agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). As previously noted, these provisions are different because the agents listed under 7 CFR 331.3 do not pose a severe threat to human health and, therefore, it is unnecessary to require that the plant-related plan address personnel safety and health.

We expect that a number of the individuals or entities seeking to register under these regulations will have previously been issued permits under 7 CFR part 330 or 9 CFR part 122, or

will have been registered under CDC's select agent regulations in 42 CFR part 72 and thus will have appropriate biosafety and/or containment procedures already in place. It is likely that these biosafety and/or containment procedures will meet the requirements of the regulations or could be easily modified to meet the requirements of the regulations. Therefore, we encourage individuals or entities seeking to register to make use of existing biosafety and/or containment procedures, and to modify such procedures as necessary.

In 7 CFR 331.11(a)(2) and 9 CFR 121.12(a)(2), we further provide that the security systems and procedures must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the threat posed by the agent or toxin. This site-specific risk assessment should involve a threat assessment and risk analysis in which threats are defined, vulnerabilities examined, and risks associated with those vulnerabilities are identified.

The security systems and procedures must be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs and must mitigate the risks identified in the risk assessment. The plan must describe inventory control procedures, personnel suitability for those individuals with access to listed agents or toxins, physical security, and cybersecurity. The plan must also contain provisions for routine cleaning, maintenance, and repairs; provisions for securing the area (e.g., card access, key pads, locks) and protocols for changing access numbers or locks following staff changes; procedures for loss or compromise of keys, passwords, combinations, etc.; procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or alteration of inventory records; provisions for the control of access to containers where listed agents and toxins are stored; and procedures for reporting and removing unauthorized persons.

Moreover, with respect to areas containing listed agents or toxins, an entity or individual must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

- Allow unescorted access only to approved individuals who are performing a specifically authorized function during hours required to perform that job;
- Allow individuals not approved under 7 CFR 331.10 or 9 CFR 121.11 to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually monitored by approved individuals;
- Provide for the control of access to containers where listed agents and toxins are stored by requiring that such containers be locked when not in the direct view of an approved individual and by using other monitoring measures, as needed;
- Require the inspection of all packages upon entry and exit;
- Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging and movement, is conducted under the supervision of an approved individual;
- Require that approved individuals do not share with any other person their unique means of accessing the area or listed agents or toxins; and
- Require that approved individuals immediately report any of the following to the responsible official: Any loss or compromise of keys, passwords, combinations, etc.; any suspicious persons or activities; any loss or theft of listed agents or toxins; any release of a listed agent or toxin; and any sign that inventory and use records for listed agents and toxins have been altered or otherwise compromised.

We recommend that security experts be consulted to ensure that the individual or entity develops security systems and procedures that will meet the requirements of this section.

However, we recognize that this may not be possible in every instance. Therefore, we reiterate that we will provide technical assistance and guidance upon request.

In 7 CFR 331.11(a)(3) and 9 CFR 121.12(a)(3), we also require that the plans include incident response plans for containment breach, security breach, inventory violations, non-biological incidents such as workplace violence, and cybersecurity breach. Under 7 CFR 331.11(a)(3), the incident response plans must address containment, inventory control, and notification of managers and responders; while under 9 CFR 121.12(a)(3) the incident response plans must address containment, personnel safety and health, inventory control, and notification of managers and responders. As discussed above, it is unnecessary for 7 CFR 331.11(a)(3) to address personnel safety and health because the plant-related agents do not pose a severe threat to human health.

Finally, to ensure that the Biocontainment and Security Plan continues to meet the entity's containment and security needs, in 7 CFR 331.11(b) we require that the plan be reviewed, performance tested, and updated annually. The plan must also be reviewed and revised, as necessary, after any incident. We include these same requirements in 9 CFR121.12(b) in order to ensure that the Biosafety and Security Plan continues to meet the entity's biosafety, containment, and security needs.

Training

To ensure that individuals who handle or use listed agents or toxins have the appropriate training and skills, 7 CFR 331.12(a) provides that the responsible official must provide appropriate training in containment and security procedures to all individuals with access to listed agents and toxins while 9 CFR 121.13(a) provides that the responsible official must provide appropriate training in biosafety, containment, and security procedures to all individuals

with access to listed agents and toxins. These provisions are different because the agents listed under 7 CFR 331.3 do not pose a severe threat to human health and, therefore, it is unnecessary to require that the plant-related plan address personnel safety and health.

Both 7 CFR 331.12 and 9 CFR 121.13 provide that the responsible official must provide information and training to an individual at the time the individual is assigned to work with a listed agent or toxin. In addition, the responsible official must provide refresher training annually.

Transfer of Biological Agents and Toxins

In accordance with 212(b) of the Act, 7 CFR 331.13 and 9 CFR 121.14 set forth the transfer requirements for biological agents and toxins. Both 7 CFR 331.13 and 9 CFR 121.14 provide that a listed biological agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that particular agent or toxin. However, the sender of an agent or toxin may be an individual or entity that has a certificate of registration for the agent or toxin, an individual or entity that is exempt from the requirements of the regulations, or an individual or entity located outside of the United States. Biological agents or toxins may only be transferred under the conditions in each section and must be authorized by APHIS or, for overlap agents or toxins, by APHIS or CDC, prior to the transfer.

Both 7 CFR 331.13(a) and 9 CFR 121.14(a) incorporate the existing permit requirements under the plant pest regulations in 7 CFR part 330 and the organisms and vectors regulations in 9 CFR part 122, respectively. We believe the current permitting systems provided for by the existing plant pest and organisms and vectors regulations will complement the requirements under these new regulations, and will provide additional protections for the transfer of listed agents and toxins. We do not expect that these permit requirements will be burdensome, since

permits for listed biological agents or toxins issued under 7 CFR part 330 and 9 CFR part 122 are valid for up to 1 year and can be renewed.

Thus, §§ 331.13(a) and 121.14(a) provide that, in addition to the permit required under 7 CFR part 330 or 9 CFR part 122, respectively, biological agents or toxins may only be imported or moved interstate with the prior authorization of APHIS or, for overlap agents or toxins, APHIS or CDC. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS or CDC, in accordance with §§ 331.13(c) and 121.14(c).

Furthermore, under 7 CFR 331.12(b), plant agents or toxins listed in 7 CFR 331.3 may be moved intrastate only with the prior authorization of APHIS, and under 9 CFR 121.14(b), animal agents or toxins listed in 9 CFR 121.3(c) may be moved intrastate only with the prior authorization of APHIS and overlap agents or toxins listed in 9 CFR 121.3(b) may be moved intrastate only with the prior authorization of APHIS or CDC. Again, to obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS or CDC, in accordance with §§ 331.13(c) and 121.14(c).

To track the actual transfer of the agents and toxins, we are adopting CDC's transfer process to be consistent with CDC and because a number of regulated parties are already familiar with this transfer process. This transfer process is designed to provide an accurate record of the transfer; such information may be crucial in the event of a criminal or epidemiological investigation.

Both 7 CFR 331.13(c) and 9 CFR 121.14(c) set out the transfer process and procedures (APHIS Form 2041). Specifically, both parts provide that, prior to each transfer, the sender and

the responsible official for the recipient must complete APHIS Form 2041. Then the sender must submit the form to APHIS or, for overlap agents or toxins, to APHIS or CDC.

After reviewing the form, APHIS will authorize the transfer based on a finding that the recipient has a certificate of registration covering the transfer of the listed agent or toxin. For overlap agents and toxins, APHIS or CDC will authorize the transfer based on a finding that the recipient has a certificate of registration covering the transfer of the listed agent or toxin.

To confirm the transfer, 7 CFR 331.13(c)(3) and 9 CFR 121.14(c)(3) provide that the responsible official for the recipient must notify the agency authorizing the transfer (either APHIS or CDC) and the sender upon receipt of the agent or toxin by mailing or faxing a completed APHIS Form 2041 to APHIS or CDC within 2 business days.

Furthermore, 7 CFR 331.13(c)(4) and 9 CFR 121.14(c)(4) provide that the recipient must notify APHIS or, for overlap agents, APHIS or CDC, immediately if the agent or toxin has not been received within 48 hours after the expected delivery or if the package containing the agent or toxin is leaking or has been damaged.

Finally, both 7 CFR 331.13(d) and 9 CFR 121.14(d) provide that the sender must comply with all applicable laws governing packaging and shipping.

Although not contained in this interim rule, pursuant to section 212(b) of the Act, we note that APHIS has incident response procedures in place to protect animal and plant health and animal and plant products in the event of a transfer or potential transfer in violation of the safety procedures and safeguard and security measures established by these regulations. Generally, these incident response procedures consist of coordinating with appropriate Federal, State, and local agencies; communicating with stakeholders, industry partners, and diagnostic laboratories

about the potential threat; elevating surveillance; and communicating with international agencies, if necessary.

Records

The recordkeeping requirements in 7 CFR 331.14 and 9 CFR 121.15 are designed to document an entity's compliance with the regulations and to satisfy the investigational needs of APHIS and the Attorney General, in accordance with section 212 of the Act. In 7 CFR 331.14 and 9 CFR 121.15, we provide that the responsible official must maintain complete records of information necessary to give an accounting of all of the activities related to agents or toxins listed in §§ 331.3 and 121.3, respectively. Such records must include the Biocontainment and Security Plan or the Biosafety and Security Plan, as applicable; a current list of all individuals with access to agents or toxins; training records for such individuals; accurate and current inventory records (including source and characterization data); permits and transfer documents (APHIS Form 2041) issued by APHIS or, for overlap agents and toxins, APHIS or CDC; security records (e.g., transactions from automated access control systems, testing and maintenance of security systems, visitor logs); and biosafety, containment, and security incident reports.

We require that the responsible official maintain such records for 3 years and produce such records, upon request, to APHIS or CDC inspectors, and appropriate Federal, State, or local law enforcement authorities.

Inspections

Section 212(f) of the Act provides that the Secretary shall have the authority to inspect persons to ensure compliance with the regulations, including prohibitions on restricted persons and other provisions of subsection 212(e) of the Act. Accordingly, in 7 CFR 331.15(a) we

require that any APHIS inspector be allowed, without previous notification, to enter and inspect the entire premises, all materials and equipment, and all records required to be maintained by the regulations. Likewise, in 9 CFR 121.16(a) we require that any APHIS or CDC inspector be allowed to conduct such inspections.

As previously noted, APHIS may inspect and evaluate the premises and records prior to issuing a certificate of registration in order to ensure compliance with the regulations (7 CFR 331.15(b) and 9 CFR 121.16(b)). APHIS or CDC may conduct such inspections for overlap agents or toxins. Once registered, inspections of the premises and records will be conducted to ensure compliance with the regulations.

Notification in the Event of Theft, Loss, or Release

The Act specifically requires notification in the event of theft, loss, or release of a biological agent or toxin. Therefore, 7 CFR 331.16(a) and 9 CFR 121.17(a) provide that the responsible official must orally notify APHIS and appropriate Federal, State, and local law enforcement agencies immediately upon discovery of the theft or loss of agents or toxins listed in §§ 331.3 and 121.3, respectively. The regulations further provide that the oral notification must be followed by a written report within 7 days. We are allowing 7 days for the submission of the written report to give the responsible official ample time to compile information and investigate the theft or loss in order to provide a more detailed report.

Similarly, 7 CFR 331.16(b) and 9 CFR 121.17(b) provide that the responsible official must orally notify APHIS immediately upon discovery that a release of a listed agent or toxin has occurred outside of the biocontainment area. As with notification of theft or loss, the regulations provide that oral notification of a release must be followed by a written report within 7 days. The regulations further provide that APHIS will notify relevant Federal, State, and local

authorities, and the public, if necessary. In § 121.17(b), we additionally provide that, if the release involves an overlap agent or toxin, we will also notify the Secretary of Health and Human Services.

Administrative Review.

Section 212(e)(7)(A)(i) of the Act states that the regulations shall provide for an opportunity for review by the Secretary, when requested by the individual involved, of a determination to deny that individual access to listed agents or toxins and, when requested by the person involved, of a determination to deny or revoke registration for that person.

Accordingly, both 7 CFR 331.17 and 9 CFR 121.18 provide that an individual or entity may appeal a denial or revocation of registration. An individual who has been denied access to listed agents or toxins or who has been granted only limited access to listed agents or toxins may appeal that decision. We note that an entity may not appeal the denial or limitation of an individual's access to listed agents or toxins.

Both 7 CFR 331.17 and 9 CFR 121.18 provide that the appeal must be in writing and submitted to the Administrator within 30 days of the decision. The appeal must state all of the facts and reasons upon which the individual or entity disagrees with the decision. Where the denial or revocation of registration or the denial or limitation of an individual's access approval is based solely upon an identification by the Attorney General, APHIS will forward the request for review to the Attorney General to review.

In accordance with section 212(e)(7)(A)(iii), the decision of the Administrator constitutes final agency action for purposes of 5 U.S.C. 702.

Section 212(e)(7)(A)(ii) of the Act provides that the Secretary, during a review of a determination, may consider information relevant to the review ex parte to the extent that

disclosure of the information could compromise national security or an investigation by any law enforcement agency.

Civil and Criminal Penalties

While not reflected in the regulations, we note that the Act provides for civil and criminal penalties for violations of the regulations. Under section 212(i) of the Act, any person who violates any provision of these regulations will be subject to a civil money penalty, in addition to any other penalties that may apply under law. The civil money penalty shall not exceed $250,000 for an individual and $500,000 for any other person.

Section 231 of the Act sets out the criminal penalties for violations of the regulations. Section 231(b)(2) of the Act provides that whoever transfers a biological agent or toxin to a person who the transferor knows or has reasonable cause to believe is not registered shall be fined or imprisoned for no more than 5 years, or both. Similarly, section 231(c)(2) provides that whoever knowingly possesses a biological agent or toxin without registering under the regulations shall be fined or imprisoned no more than 5 years, or both.

Immediate Action

Immediate action is necessary in order for USDA to comply with the requirements of Title II, subtitle B, of Public Law 107-188, which requires the publication of this interim rule not later than December 9, 2002. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest.

We will consider comments we receive during the comment period for this interim rule (see DATES above). After the comment period closes, we will publish another document in the Federal Register. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

For this rule, we have prepared an economic analysis. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866, as well as an analysis of the potential economic effects of this proposed rule on small entities, as required under 5 U.S.C. 603. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188), the Secretary of Agriculture is required to provide by regulation for the establishment and enforcement of standards and procedures governing the possession and use of the listed biological agents and toxins; the establishment and enforcement of safety requirements for the transfer of listed agents and toxins; the establishment and enforcement of safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or other criminal purpose; and the establishment of procedures to protect animal and plant health, and animal and plant products, in the event of a transfer in violation of the established safety and security measures. For the Health and Human Services Department (HHS), CDC is taking similar measures related to biological agents and toxins that have the potential to adversely affect human health or human and animal health.

Small Entities

The Regulatory Flexibility Act requires that agencies specifically consider the economic effects of their rules on small entities. The entities most likely to be affected by this rule are

those laboratories and other institutions conducting research and related activities that involve the use of listed biological agents and toxins. Most affected entities (other than Federal or State governmental entities) would be considered part of North American Industrial Classification System (NAICS) code 541710, "Research and Development in the Physical, Engineering, and Life Sciences." Some affected entities would be considered part of NAICS 541940, "Veterinary Services;" NAICS 611310, "Colleges, Universities and Professional Schools;" NAICS 325412, "Pharmaceutical Preparation Manufacturing;" NAICS 325413, "In-Vitro Diagnostic Substance Manufacturing;" and NAICS 325414, "Biological Product (except Diagnostic) Manufacturing."

The Small Business Administration (SBA) has established guidelines for determining when establishments are to be considered "small" under the Regulatory Flexibility Act. An entity in NAICS 541710, 325413, or 325414 is considered to be a small entity if it has 500 or fewer employees; for NAICS 325412, that threshold is 750 or fewer employees. An entity in NAICS 611310 is considered small with annual receipts/revenues of $6 million or less.

According to the 1997 Economic Census, no less[1] than 95 percent of life sciences research and development establishments subject to Federal income tax, and no less than 92 percent of those establishments not subject to Federal income taxes, can be considered small. More than 99 percent of "biological (except diagnostic) manufacturing" establishments, more than 98 percent of "diagnostic manufacturing" establishments, and at least 94 percent of "pharmaceutical manufacturing" establishments are considered small. The economic census does not contain information on the establishment size of veterinary service entities. According

[1] The establishment size breakdown in the economic census does not precisely fit the SBA guidelines.

to data from the U.S. Department of Education, about 31 percent of reporting postsecondary institutions had revenue of less than $6 million in fiscal year 1995-96.

Benefits of the Rule

Benefits associated with this rule are the avoided losses to animals or plants that could be attacked by these organisms, and their products and markets. Losses include reduction in yield and productivity of affected hosts, public and private control costs, and loss in export revenue due to trade embargoes. The listed agents and toxins include viruses, bacteria, and fungi that potentially pose a severe threat to plant health or plant products. The listed pathogens could threaten a number of important crops including citrus, corn, potatoes, rice, stone fruit, and soybeans. In 2001, soybean production alone was valued at more than $12 billion. The rule also covers biological agents and toxins that have been determined to have the potential to pose a sever threat to both human and animal health, to animal health, or to animal products. Paragraph (b) of 9 CFR 121.2 lists 21 overlap agents and toxins. This list was drawn from CDC's list of select agents, the overlap being those select agents that pose a risk to both human and animal health. The 23 agents and toxins listed in 9 CFR 121.2(d) include the causative agents of 14 of the 15 diseases classified by the Office International des Epizooties (OIE) as "List A" diseases. (The causative agent of the fifteenth List A disease, Rift Valley fever, is an overlap agent listed in the above part.) List A diseases are, according to OIE, those transmissible diseases that have the potential for very serious and rapid spread, irrespective of national borders, that are of serious socioeconomic or public health consequence and that are of major importance in the international trade of animals and animal products. Five of the remaining nine agents and toxins are OIE List B diseases, i.e., transmissible diseases that are considered to be of socioeconomic and/or public health importance within countries and that are significant in the international trade

of animals and animal products. The three remaining diseases/disease agents – two restricted foreign animal pathogens and one emerging paramyxovirus – were included on the list based on the determination that they potentially pose a severe threat to animal health or animal products.

The costs associated with outbreaks can be very high as is demonstrated by natural outbreaks that have occurred. For example, it has been estimated that the losses to agriculture and the food chain from the recent FMD outbreak in the United Kingdom, including the costs compensated by the government amount to about £3.1 billion ($4.7 billion). In 1999, Ekboir estimated the potential impacts of an FMD outbreak in California alone at between $8.5 and $13.5 billion.[2] Also, a BSE crisis occurred in the UK (which has a cattle industry about 1/10 the size of that in the United States) in 1996. It has been estimated[3] that the total resource costs to the UK economy as a result of BSE in the first 12 months after the onset of the 1996 crisis were in the range of £740 million to £980 million ($1.2 billion to $1.5 billion), or just over 0.1 percent of the gross domestic product of the United Kingdom. In addition to these losses, the UK lost its entire export market for beef following the crisis.

The above cited consequences relate to natural or accidental introduction. Deliberate introduction greatly increases the probability of an agent or toxin becoming established and causing wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and possible loss of life. The perpetrators would have the advantage of controlling the time of introduction of the agent, introducing agents into remote or highly susceptible areas, multiple introductions of the same agent, or simultaneous

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[2] Ekboir, J.M., "Potential impact of foot-and-mouth disease in California: The role and contribution of animal health surveillance and monitoring services." Davis, CA: Agricultural Issues Center, Division of Agriculture and Natural Resources, University of California, Davis, 1999.

[3]. DTZ Pieda Consulting, "Economic Impact of BSE on the UK economy." A Report commissioned by the UK Agricultural Departments and HM Treasury.

release of different agents. Intentional introductions permit an increased probability of survival of a pathogen, the use of highly virulent strains and high concentrations of inoculum, and precise timing of release to coincide with maximal colonization potential.[4]

Costs of the Rule

Facilities that possess listed agents and toxins will be affected by this rule. Those facilities are primarily research and diagnostic facilities. They include Federal, State, and university laboratories, and commercial enterprises.

Because affected entities vary widely and the information needed to determine an individual facility's biosafety, containment and physical security situation will not be available until the registration process occurs, information on specific necessary changes at any individual facility and thus those costs are not available. However, some general observations regarding the potential costs can be made.

Affected Entities

There are approximately 33 academic, commercial, and State and Federal government facilities that have indicated their possession of listed plant pathogens and thus affected by this rule. This information was obtained from the notifications received by Plant Protection and Quarantine, APHIS-USDA.

In addition, there are approximately 619 commercial diagnostic facilities, university research and diagnostic facilities, State and Federal diagnostic and research facilities, and others

[4] National Research Council.

in possession of animal and/or overlap agents or toxins that are expected to be affected by this rule.[5]

The facilities that deal with listed plant agents and toxins are academic institutions, commercial diagnostic and research facilities, and State and Federal Government facilities. Almost 60 percent of the affected facilities are academic and almost 30 percent government. The affected facilities tend to be small.

The facilities that deal with animal and overlap agents are academic, commercial, government, non-profit, and other. Twenty-nine percent of the facilities with listed agents and toxins are identified academic institutions, 45 percent as private commercial or non-profit entities, and 15 percent as government. The remaining 11 percent are not identified, but include veterinary practices. Animal and overlap agents are used primarily in diagnostic work and research.

The level of security at the facilities dealing with listed agents and toxins is currently very diverse, ranging from a locked freezer to a lock on the door to razor wire perimeter fencing, a guard post, locks or coded entry, and visitor escorts.

[5] As of October 18, 2002, 1,653 entities had submitted notifications that they possess biological agents or toxins affecting animals and/or humans listed by either USDA or HHS. In this analysis, we use 1,653 entities. In coordination with CDC, we assumed that those facilities with animal agents and those with animal and overlap agents will be affected by the APHIS rule. Those facilities with human agents and those human and overlap agents were assumed to be affected by the CDC rule. About one-half of those facilities with only overlap agents were assumed to be affected by the APHIS rule (50 percent of facilities with only overlaps, except all medical practices which were attributed to the CDC rule and all veterinary practices which were attributed to the APHIS rule). Facilities with both animal and human agents were considered in both analyses. This may cause some double counting if entities with both animal and human agents do not also have separate laboratories for that work. Numbers provided by Ed Gaunt, ASI - contractor collecting and compiling notification information.

Exemptions from the Rule

Clinical and diagnostic laboratories are specifically exempted from the provisions of the regulations for possessing, using, or transferring animal or overlap agents or toxins that are contained in specimens presented for diagnosis or verification, and for agents that are contained in specimens presented for proficiency testing; provided that the facilities follow the requirements on disposal, transfer and notification. Facilities that handle fixed tissues that are, bear, or contain listed animal agents or toxins will be exempt from the registration requirements, provided that a permit has been issued to the facility under 9 CFR part 122. In addition, the Secretary may grant exemptions from the applicability of the regulations as they apply to animal only and plant agents and toxins if the Secretary determines that such exemptions are consistent with protecting animal and plant health, and animal and plant products. Registered diagnostic laboratories will also be required to report identifications of listed agents and toxins when presented for diagnosis. APHIS expects to receive 1,000 required notifications of identification and 250 exemption applications in a given year. It is estimated that complying with the exemption requirements will cost $72 per notification and $84 per exemption application.[6]

Registration

Under this rule, unless exempted a person or facility shall not possess, use, or transfer any listed agent or toxin without a certificate of registration issued by APHIS or CDC. The registration process is designed to obtain critical information concerning persons or facilities in possession of certain agents or toxins, as well as the specific characteristics of the agents and toxins. Information to determine that persons seeking to register have a lawful purpose to

[6] Based on Bureau of Labor Statistics data. Labor rates used are the same as used by CDC in their analysis of listed agents and toxins. See Supporting Statement for Information Collection Request "Part 73–Select Biological Agents and Toxins" for CDC rule covering 42 CFR Part 73.

possess, use, or transfer agents or toxins will also be required as part of the registration process. This will involve security risk assessments by the U.S. Department of Justice, and collecting and providing the required information. Also as a condition of registration, a Biocontainment and Security Plan or Biosafety and Security Plan must be developed. It is estimated that it will cost between $414 and $778 per facility to collect and provide the required information. Registration amendments are expected to cost $86 each. In addition, it is estimated that re-applying for registration will cost $299 to $459 for those facilities to re-apply, as the registration is valid for up to 3 years.[7] It is estimated that the development of the biosafety/biocontainment plan will cost $2,777 at those facilities needing one. The security plan should be covered in the facility security assessment below. Complying with inactivation requirements is estimated to cost $43 per notification.

Transfer

Under this rule, listed biological agents and toxins may only be transferred to persons registered to possess, use, or transfer that particular agent or toxin. However, the sender may be an individual or facility exempt from the requirements of this rule, or an individual or facility located outside the United States. Transfer must occur only with prior authorization, notification of receipt by the recipient, and notification of overdue or damaged shipments. It is estimated that complying with these requirements will cost $124 for each of an expected 6,520 transfers in a year.

[7] Registrations will be valid for up to 3 years. It is estimated that approximately two-thirds of all facilities will be required to reapply within the first 3 years.

Biosafety and Containment Procedures

Biosafety and containment requirements ensure that the combination of work practices and physical containment are proportional to the risk associated with the agent or toxin. USDA permits dealing with the listed agents and toxins already required the biosafety and containment level commensurate with the risk associated with the pathogen covered in the permit or registration. Therefore, to the extent that affected entities are already permittees, the biosafety and containment requirements of this rule will have already been required at those facilities. There are almost 400 individual permittees with listed agents and toxins representing an unknown number of facilities.[8] In addition, some portion of the potentially affected entities will be exempt from the requirements of this rule, and therefore not affected by the biosafety requirements.

Physical Security Procedures

This rule will require that any facility where listed agents and toxins are held adequately provide for the physical security of the premises. This rule does not specify how security needs are to be met, only that they are adequate. Because the current level of security is very diverse, physical security components may have to be added in various quantities (including none) to meet the specific security needs of a given facility.

An example of security spending at USDA laboratories shows security upgrades at NVSL in Ames, IA, completed in 2002 cost $550,077 ($6.63/ft^2, 83,000 ft^2 total area). Installations of electronic security components can include closed-circuit television (CCTV) (e.g., cameras, VCR, and control equipment), intrusion detection system (access-control card readers, card-keys, operating computer and software), all cabling associated with the security

[8] Because of the data on notification of possession of listed agents and toxins, we cannot directly link permittees to facilities.

system, and integrating the system with the off-site monitoring. Other security related expenses that could be needed at a given facility included a facility security assessment (to prepare the security plan required in the rule) and entry control equipment (x-ray, metal detectors). Other features would entail yearly recurring costs (i.e., off-site monitoring, an equipment maintenance agreement, and guard service).

The average cost per square foot of electronic portion of security for budget purposes ranges from $\$6.25/ft^2$ for facilities under 80,000 ft^2 to $\$8.33/ft^2$ for facilities in excess of 150,000 ft^2. This is based on average actual security system installations for APHIS facilities, and includes CCTV, intrusion detection systems, integration, perimeter protection, design, construction, and construction management, but not biometric technology, and assumes single-story facilities and has been adjusted for laboratory-type facilities.

This rule will require that all information resources related to listed biological agents and toxins have an appropriate level of protection in the system that is used to acquire, store, manipulate, manage, move, control, display, switch, interchange, receive or transmit that information. Most affected entities have a variety of compelling reasons, including regulatory requirements, for already protecting information.

Other Costs

Other costs associated with this rule include the costs of any additional training that may occur, record keeping, complying with the requirements for theft/loss/release notification, and appealing rulings. It is estimated that yearly recordkeeping will cost from $450 to $1,499 per registered facility. It is estimated that theft, loss, and release reporting will cost $72 for each occurrence. It is estimated that appeal requirements will cost $311 for each occurrence, and that the requests for expedited reviews will cost $43 each.

Costs to APHIS

Costs to APHIS that may be incurred as a result of the rule include the cost for processing facility registrations, notifications of identification of agents and toxins, exemption applications, transfer applications, theft/loss/release notifications and appeals, and performing facility inspections. It is estimated that APHIS will incur costs associated with this rule of as much as $1.5 million in the first year. Paperwork processing will cost APHIS $744,705 per year. In addition, APHIS may incur costs associated with providing technical assistance on compliance with this rule. Inspections are expected to cost between $240 and $997 per facility and occur every 3 years with along with registration, or $156,000 to $650,000 for all facilities. Additional inspector training to cover the needs of this rule may be needed as well. The cost may be similar to the current level. In 2002, APHIS spent $35,480 on inspector training. Background checks or security clearances for all inspectors could be expected to cost $45,000. User fees to offset government costs will not be collected by APHIS under this rule.

Potential Impact of this Rule

Approximately 70 percent of research and development (commercial and non-profit laboratories dealing with human, animal, and plant agents), biological (except diagnostic) manufacturing, diagnostic manufacturing, pharmaceutical manufacturing, and other private establishments affected by this rule have fewer than 20 employees, and another 15 percent have between 20 and 49 employees.[9] Plant laboratories (Federal, commercial, non-profit, and academic) tend to be very small with fewer than 10 persons having access to the agents or toxins. Veterinary diagnostic laboratories (commercial, State or university) and university research

[9] 1997 Economic Census. Department of Commerce, Census Bureau.

laboratories likely have fewer than 100 employees.[10] Federal facilities covered by the rule will be affected by the registration requirements but should not have to make alterations due to the biosafety, containment and security requirements of this rule because they already must meet or exceed the requirements of this rule. In addition, an unknown portion of facilities will be exempt from the provisions of the rule. The level of security at the facilities dealing with listed agents and toxins is currently very diverse, ranging from a lock on the door to razor wire perimeter fencing, a guard post, locks or coded entry and visitor escorts.

For the purpose of assessing the impact of the security requirements of the rule, we make the following assumptions based on the available information on the size distribution of the affected entities:

- Eighty percent of affected facilities have an area to be secured of approximately 10,000 ft^2;[11]
- Five percent of affected facilities are Federal facilities and will not need security upgrades as a result of this rule;
- Fifteen percent of affected facilities have an area to be secured of approximately 30,000 ft^2;[12] and

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[10] AAVLD provided information on 10 diagnostic laboratories. These laboratories ranged in size form 11 to 100 employees including faculty, staff (part- and full-time), and students. In addition, the AAVLD president estimated that diagnostic labs in general would likely have between 6 and 80 employees. According to Dr. Denise Spenser, USDA-APHIS, university research on listed agents likely involves fewer than 100 persons (3 to 5 principal investigators out of about 25 faculty members in each of 3 or 4 departments – microbiology (veterinary microbiology), chemistry, and physiology, 3 to 5 (20 at most) investigators, technicians, and students in each laboratory).

[11] In addition to laboratory space, these facilities can have offices, conference rooms, administration space, mechanical/electrical rooms and storage space. The building code allowance for business use type buildings, which includes laboratories, is 100 ft^2 per occupant. We assume that the actual space at these facilities is 2 to 5 times this allowance. This would cover facilities with fewer than 50 employees.

[12] This space is larger and assumed to be able to house more than 50 employees.

- Because facilities will have varying levels of existing security, security needs, and methods of meeting those needs, the average security upgrades in APHIS facilities is used as a proxy for upgrades at these facilities. (The proxy is based on upgrading to state of the art equipment, which may or may not be used at a given facility.)

Using an average budget estimate for upgrading the electronic portion of a security system of $\$6.25/ft^2$, a facility with 10,000 ft^2 to secure by installing electronic security countermeasures would need to budget $62,500 and a facility with 30,000 ft^2 to secure would need to budget $187,500. To obtain an aggregate cost estimate we apply these budget estimates to the 95 percent of facilities with area to be secured based on the size of that area. It should be noted that, as indicated above, utilizing APHIS' costs as a proxy implies that all facilities have baseline levels of electronic security similar to that of APHIS facilities and will upgrade to state-of-the-art technology. However, because the baseline level of security present at each facility is unknown and ultimate security needs are varied, this may or may not be the case. A given facility may be exempt and need no upgrade, may already have adequate security in place, or may need an upgrade but not to state-of-the-art.

Applying a budget cost of $62,500 to the 80 percent of affected facilities with 10,000 ft^2 to secure gives an overall cost of $32.6 million. Applying a budget cost of $187,500 to the 15 percent of affected entities with 30,000 ft^2 to secure gives a cost of $18.4 million.

In addition, a facility could need none, some, or all of the following:

- Facility security assessment, including developing a security plan as per the rule; $8.9 million if the 80 percent with smaller spaces all need a $17,000 assessment and $2.5 million if the 15 percent with larger spaces all need a $25,000 assessment.

- Entry control equipment; includes x-ray - small unit ($28,000 per unit), x-ray - large unit ($40,000 per unit), and metal detector(s) ($20,000 per unit). Other features would entail yearly recurring costs.
- Yearly recurring costs: Off-site monitoring ($10,000 to $45,000 per year); an equipment maintenance agreement ($12,000 to $30,000 per year); and guard service - unarmed ($30.00/hr per security post), armed ($35.00/hr per security post), and a supervisor ($40.00/hr).

This rule will involve other costs to the regulated community. It is estimated that complying with the exemption and notification of identification requirements will have a total cost of $93,000 per year. The rule will also involve the costs associated with the registration requirements. It is estimated that it will cost $315,980 to collect and provide the required information. Registration amendments are expected to cost $100,964 in the first year. In addition, it is estimated that it will cost $214,809 for facilities to collect and provide the required information for re-application. Complying with the requirements concerning the transfer of listed agents and toxins could cost $808,480 per year. The rule could also entail costs for any needed upgrades to biosafety and containment, and cybersecurity. These costs are expected to be small. To the extent that affected entities are already permittees, the biosafety and containment requirements of the new act will have already been required at those facilities. Affected entities have a variety of compelling reasons, including legislation, for already protecting information. The rule also requires that a biosafety and security plan be developed. It is estimated that the development of the biosafety portion of the plan could cost in total $1.5 million if one-half of the 652 affected facilities need to develop new plans. The security portion would be developed as part of the facility security assessment above. It is estimated that

notifications of inactivation would cost $1,376 per year. Other costs of the rule also include record keeping costs, estimated at $425,265 per year. The estimated total cost associated with notifications of theft, loss and release of listed agents or toxins is $144 per year. The estimated total cost associated with appeals under this rule is estimated to be $311 per year. The estimated total cost associated with expedited reviews under this rule is estimated to be $14,018 per year.

The costs to APHIS include processing facility registrations, notifications of identification of agents and toxins, exemption applications, transfer applications, theft/loss notifications, appeals, performing facility inspections, and providing technical assistance for compliance. It is estimated that this will cost as much as $1.5 million in the first year. Paperwork processing is estimated to cost APHIS $744,705 per year.[13] In addition, APHIS may incur costs associated with providing technical assistance on compliance with this rule. Facility inspections will occur every 3 years and are estimated to cost between $240 and $997 each, or between $156,480 and $650,044 for all registered facilities.[14] Additional inspector training could cost $35,480 annually and security clearances $45,000 for all inspectors.

Table 1.—Summary of potential costs

Activity	One-time costs	Recurring costs
Exemptions from the regulations		
Applications		$72,000/year
Notifications of identification		21,000/year
Registration		
Application	$315,980	

[13] Costs to Government for Information Collections for Select Agent Registrations.

[14] These costs are based on current APHIS user fees for facility inspections: Biosecurity Level (BSL) 3, a flat $997, and BSL2 $60 to $80/hr for about 4 hours. Under this rule, users will not be charged for the inspections and thus the Government will absorb the cost of those inspections.

Renewal		214,809/every 3 years
Amendments to registration		100,964/year(first year)
Biosafety/Biocontainment plan	1.5 million	
Inactivations		1,376
Security plan/security assessment	11.4 million[1]	
Transfer		808,480/year
Physical security procedures[2]		
Electronic security (cameras, card readers, etc.)[3]	51 million[4]	
Entry control (X-ray, metal detectors)	20,000-40,000 each (as needed)	
Off-site monitoring		10,000-45,000/year (as needed)
Maintenance agreement		12,000-30,000/year (as needed)
Guard service		30-40/hour (as needed)
Other costs		
Recordkeeping		425,265/year
Theft/loss/release notification		144/year
Appeals		311/year
Expedited reviews		14,018/year
Costs to APHIS		
Processing paperwork		744,705/year
Inspections		156,000-650,000 every 3 years
Inspector training		$35,480/yr
Inspector security clearances	$45,000	

[1] Assumes $17,000 for small facility, $25,000 for large facility.
[2] Because security needs are site specific and the rule allows for site specific security solutions, the approaches and applications will be varied. Actual additional physical security measures added will vary (including none) based on the current level of security and the specific security needs of a given facility.
[3] Estimate of the aggregate cost is based on an average facility cost per square foot to upgrade to state of the art technology.

[4] Based on $62,500 for 10,000 ft^2 (assuming 80 percent of facilities), $187,500 for 30,000 ft^2 (assuming 15 percent of facilities), and $0 for no upgrades (assuming 5 percent of facilities).

The above is given to provide perspective on the magnitude of the potential costs associated with the rule. The facilities covered in this rule can and do vary from a small laboratory contained within a larger facility to large dedicated buildings to large groups of buildings and land. Because security needs are site specific and the rule allows for site specific security solutions, the approaches and applications will be varied. Physical security measures may have to be added in various quantities (including none) to meet the specific security needs of a facility. Also, some of the impacts of this rule are somewhat offset by previous requirements, funding from other sources for upgrades that would otherwise be mandated by this rule, and flexibility in the rule that allows for site-specific needs to be met in the most cost effective manner possible.

Summary

While the costs associated with this rule could be considerable, some of those impacts are somewhat offset by previous requirements, funding from other sources for upgrades that would otherwise be mandated by this rule, and flexibility in the rule that allows for site specific needs to be met in the most cost effective manner possible. In addition, these costs are greatly outweighed by the benefits of preventing a deliberate introduction of a listed agent or toxin into the United States. Should any listed agent or toxin be intentionally introduced, the consequences would be significant as demonstrated by natural outbreaks that have occurred. Consequences could include costs of eradication efforts, disruption of markets, difficulties in sustaining an adequate food and fiber supply, and the potential spread of disease infestations over large areas. Deliberate introduction greatly increases the probability of an agent or toxin becoming

established and causing wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and possible loss of life.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection and recordkeeping requirements included in this interim rule have been submitted for emergency approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, we will publish a document in the Federal Register providing notice of the assigned OMB control number or, if approval is denied, providing notice of what action we plan to take.

We plan to request continuation of that approval for 3 years. Please send written comments on the 3-year approval request to the following addresses: (1) Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503; and (2) Docket No. 02-088-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71,

4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 02-088-1 and send your comments within 60 days of publication of this rule.

This interim rule establishes regulations governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal products and plant products. Unless specifically exempted under the regulations, an individual or entity must register with APHIS or, for overlap agents or toxins, APHIS or CDC, in order to possess, use, or transfer biological agents or toxins.

To register, an individual or entity must submit a registration application package; develop and implement a Biocontainment and Security Plan or Biosafety and Security Plan, as applicable; and request access approval for individuals who have been identified as having a legitimate need to handle or use listed agents or toxins and who have the appropriate training and skills to handle or use such agents or toxins.

We are soliciting comments from the public (as well as affected agencies) concerning our information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

For 7 CFR part 331:

Estimate of burden: Public reporting burden for this collection of information is estimated to average 4.5590 hours per response.

Respondents: Researchers, universities, research and development organizations, diagnostic laboratories and other interested parties who possess, use, or transfer agents or toxins deemed a severe threat to animal or plant health, or animal or plant products.

Estimated annual number of respondents: 33

Estimated annual number of responses per respondent: 4.8787

Estimated annual number of responses: 161

Estimated total annual burden on respondents: 734

For 9 CFR part 121:

Estimate of burden: Public reporting burden for this collection of information is estimated to average 2.56493 hours per response.

Respondents: Researchers, universities, research and development organizations, diagnostic laboratories and other interested parties who possess, use, or transfer agents or toxins deemed a severe threat to animal or plant health, or animal or plant products.

Estimated annual number of respondents: 619

Estimated annual number of responses per respondent: 15.573

Estimated annual number of responses: 9,640

Estimated total annual burden on respondents: 24,726

(Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this interim rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

List of Subjects

7 CFR Part 331

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

9 CFR Part 121

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

Accordingly, we are revising 7 CFR part 331 and 9 CFR part 121 to read as follows:

7 CFR Chapter III

PART 331—POSSESSION, USE, AND TRANSFER OF BIOLOGICAL AGENTS AND TOXINS

Sec.

Authority: Secs. 211-213, Title II, Pub. L. 107-188, 116 Stat. 647 (7 U.S.C. 8401).

§ 331.0 Effective and applicability dates.

The regulations in this part are effective on [Insert date 60 days after date of publication in the Federal Register]. On and after that date, any person possessing, using, or transferring any agent or toxin listed in § 331.3 must be in compliance with the provisions of this part. However, so as not to disrupt research or educational projects involving listed agents or toxins that were underway as of the effective date of this part, any person possessing such agents or toxins as of the effective date (current possessors) will be afforded additional time to reach full compliance with this part. Any provision not specifically cited in paragraphs (a) through (f) of this section will be applicable as of [Insert date 60 days after date of publication in the Federal Register]. In addition, any individual or entity who does not possess listed agents or toxins by the effective date of this part, but who wishes to initiate a research or educational project prior to November

12, 2003, must be in compliance with the provisions of this part that are applicable for current possessors at the time of application, as provided in paragraphs (a) through (e) of this section.

(a) During the period from [Insert date 60 days after date of publication in the Federal Register], to November 12, 2003, biological agents or toxins listed in § 331.3 may only be transferred to an individual or entity that is not registered under this part if the individual or entity has been issued a permit by the Administrator under part 330 of this chapter to import or move interstate that specific agent or toxin. If an individual or entity has not been issued a permit under part 330 of this chapter, the individual or entity may apply for a permit. To receive an agent or toxin, an individual or entity will also be required to submit APHIS Form 2041, in accordance with § 331.13(c). Because USDA permits do not cover intrastate movement, an individual or entity may not receive a listed agent or toxin that is being moved intrastate until that individual or entity is registered in accordance with this part.

(b) By March 12, 2003, the responsible official must submit the registration application package as required in § 331.8. In addition, the responsible official must submit to the Attorney General the names and identifying information for the responsible official; alternate responsible official, where applicable; entity; and, where applicable, the individual who owns or controls the entity.

(c) By April 11, 2003, the responsible official must submit to the Attorney General the names and identifying information for all individuals whom the responsible official has identified as having a legitimate need to handle or use listed agents or toxins, and who have the appropriate training and skills to handle such agents or toxins, as required in § 331.10.

(d) By June 12, 2003, the responsible official must submit to APHIS the security section of the Biocontainment and Security Plan required in § 331.11.

(e) By September 12, 2003, the responsible official must implement the security section of the Biocontainment and Security Plan, as required in § 331.11, and provide security training in accordance with 7 CFR 331.12.

(f) By November 12, 2003, the registration application process must be complete and the entity in full compliance with the regulations in this part.

§ 331.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Attorney General. The Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

Diagnostic laboratory. A laboratory facility that receives specimens for the purpose of determining the identities of pests, pathogens, contaminants, or causes of disease.

Entity. Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

Import. To move into, or the act of movement into, the territorial limits of the United States.

Interstate. From one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Permit. A written authorization by the Administrator to import or move interstate biological agents or toxins, under conditions prescribed by the Administrator.

PPQ. The Plant Protection and Quarantine Programs of the Animal and Plant Health Inspection Service

Responsible official. The individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this part.

Specimen. A sample of material collected for use in testing, such as plant tissues (e.g., stems, seeds, flowers, pollen, leaves, roots, fruits, tubers, tissue cultures, protoplasts), soil, water, swabs, cultures, and suspensions.

State. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States. All of the States.

USDA. The United States Department of Agriculture.

§ 331.2 Purpose and scope.

(a) This part sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to plant health or to plant products. The purpose of this part is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose.

(b) Accordingly, this part provides that any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 331.3 must register in accordance with § 331.6. To register, each entity must designate an individual who has the authority and control to ensure compliance with the regulations to be the responsible official. The responsible official must complete and submit the registration application package to APHIS. As part of registration, the responsible official, the entity, and, where applicable, the individual who owns or controls such entity will be subject to a security risk assessment by the Attorney General.

(c) The responsible official is responsible for ensuring compliance with the safety procedures in this part, including implementing the Biocontainment and Security Plan in accordance with § 331.11, providing the proper training to individuals who handle or use agents or toxins listed in § 331.3, and providing proper laboratory facilities to contain and dispose of such agents or toxins. In addition, the responsible official is responsible for ensuring compliance with the safeguard and security measures in this part, including restricting access to only those individuals who have a legitimate need to handle or use agents or toxins and who have been approved in accordance with § 331.10, and transferring such agents or toxins only to registered individuals or entities in accordance with § 331.13.

§ 331.3 List of biological agents and toxins.

(a) The biological agents and toxins listed in this section have been determined to have the potential to pose a severe threat to plant health or to plant products.

Liberobacter africanus, Liberobacter asiaticus
Peronosclerospora philippinensis
Phakopsora pachyrhizi
Plum pox potyvirus
Ralstonia solanacearum, race 3, biovar 2
Sclerophthora rayssiae var. zeae
Synchytrium endobioticum
Xanthomonas oryzae pv. oryzicola
Xylella fastidiosa (citrus variegated chlorosis strain)

(b) The Administrator has determined that it would be impractical to regulate a biological agent or toxin that is in its naturally occurring environment. Therefore, any biological agent or toxin listed in this section that is in its naturally occurring environment will not be subject to the requirements of this part, provided that the biological agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(c) The Administrator has determined that biological agents or toxins that meet any of the following criteria do not have the potential to pose a severe threat to plant health or to plant products. Therefore, an individual or entity that only possesses, uses, or transfers an agent or toxin that meets any of the following criteria will not be subject to the requirements of this part:

(1) Nonviable agents that are, bear, or contain listed agents or toxins;

(2) Genetic elements or subunits of listed agents or toxins, if the genetic elements or subunits are not capable of causing disease.

§ 331.4 Exemptions.

(a) Diagnostic laboratories[1] and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins is immediately reported to the Administrator and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 7 days after identification, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator.[2] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. A copy of the completed form must be maintained for 3 years.

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[1] However, diagnostic laboratories and other persons will still be required to obtain a permit under part 330 of this chapter in order to import or move interstate any listed agent or toxin.

[2] A diagnostic laboratory or other person must immediately notify APHIS by calling (301) 734–5519. APHIS Form 2040 may be obtained by calling (301) 734-5519 or faxing a request to (301) 734–8700. The form is also available on the Internet at http://www.aphis.usda.gov/ppq/permits. The completed form may be mailed to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; or faxed to (301) 734-8700.

(b) In addition to the exemption provided in paragraph (a) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal or plant health, and animal or plant products. An individual or entity that possesses, uses, or transfers agents or toxins may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.[3]

§ 331.5 Registration; who must register.

(a) Unless exempted under § 331.4, any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 331.3 must register with APHIS.

(b) Each entity must designate an individual to be its responsible official. The responsible official must have the authority and control to ensure compliance with the regulations. The responsible official must complete and sign the registration application package, and will be the individual contacted by APHIS if any questions arise concerning the application or subsequent compliance with the regulations in this part. As part of registration,

[3] A request for exemption may be mailed to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; or faxed to (301) 734-8700.

the responsible official and the entity will be subject to a security risk assessment by the Attorney General. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, APHIS will consider the individual to be the responsible official.

(c) An entity may designate an individual to be an alternate responsible official, who may act for the responsible official when he/she is unavailable. This individual must have the authority and control to ensure compliance with the regulations when acting for the responsible official. This individual will also be subject to a security risk assessment by the Attorney General as part of registration.

§ 331.6 Registration; general provisions.

(a) Unless exempted under this part, an individual or entity shall not possess, use, or transfer any agent or toxin listed in § 331.3 without a certificate of registration issued by APHIS.

(b) A certificate of registration may be issued upon:

(1) Approval of the responsible official; the alternate responsible official, where applicable; the entity; and, where applicable, the individual who controls the entity following a security risk assessment by the Attorney General;[4] and

(2) Approval of the containment and security of the entity. The entity's containment and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS will review the Biocontainment and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the containment and security requirements; and

[4] The security risk assessment of the entity and the individual who owns or controls such entity may be waived for Federal, State, or local governmental agencies.

(3) A determination by the Administrator that the individual or entity seeking to register has a lawful purpose to possess, use, or transfer such agents or toxins.

(c) A certificate of registration will be valid for only the specific agents or toxins listed on the certificate and specific activities and locations. A certificate of registration may cover more than one listed agent or toxin, and it may be amended to cover additional listed agents or toxins.

(d) A certificate of registration may be amended to reflect changed circumstances (e.g., replacement of the responsible official, changes in ownership or control of the entity,[5] changes in the activities involving the agent or toxin). The responsible official must immediately notify APHIS of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

(e) If a responsible official wishes to discontinue possessing, using, or transferring a particular agent or toxin, the responsible official may inactivate the agent or toxin or he/she may transfer the agent or toxin to a registered individuals or entities in accordance with § 331.12. The responsible official must notify APHIS 5 business days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. We will notify the responsible official if we wish to observe the inactivation of the agents or toxins.

(f) A certificate of registration will be valid for a maximum of 3 years.

§ 331.7 Denial, revocation, or suspension of registration.

(a) APHIS may deny an application for registration or revoke registration if:

[5] Any change in ownership or control of an entity will require a security risk assessment for the new individual(s) who owns or controls the entity.

(1) The Attorney General identifies the responsible official, entity, or the individual who owns or controls the entity as within any of the categories described in 18 U.S.C. 175b; or

(2) The Attorney General identifies the responsible official, entity, or the individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime set forth in 18 U.S.C. 2332b(g)(5); or

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) The responsible official does not have a lawful purpose to possess, use, or transfer agents or toxins listed in § 331.3; or

(4) The responsible official is an individual who handles or uses listed agents or toxins and he/she does not have the necessary training or skills to handle such agents or toxins; or

(5) The entity does not meet the containment and security requirements prescribed by the Administrator;[6] or

(6) There are egregious or repeated violations of the containment or security requirements; or

(7) The Administrator determines that such action is necessary to protect animal or plant health, and animal or plant products.

(b) APHIS may summarily revoke or suspend registration for any of the reasons set forth in paragraph (a) of this section.

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[6] If registration is denied for this reason, we may provide technical assistance and guidance.

(c) APHIS will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended.

(d) Denial of an application for registration, revocation of registration, and suspension of registration may be appealed under § 331.16.

§ 331.8 Registration; how to register.

(a) To apply for a certificate of registration, an individual or entity must submit all of the information and documentation required in the registration application package to APHIS, including the name, source, and characterization data for each agent or toxin to be registered.

(b) The registration application package may be obtained by calling (301) 734-5519 or faxing a request to (301) 734-8700. It is also available on the Internet at http://www.aphis.usda.gov/ppq/permits. The completed registration application package may be mailed to APHIS, Plant Protection and Quarantine, Biological and Technical Services, 4700 River Road Unit 133, Riverdale, MD 20737-1236; or faxed to (301) 734-8700. Assistance in completing the registration application may be requested by calling (301) 734-5519.

§ 331.9 Responsibilities of the responsible official.

(a) The responsible official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing a Biocontainment and Security Plan in accordance with § 331.11;

(2) Allowing only approved individuals within the entity to have access to any agents or toxins listed in § 331.3 in accordance with § 331.10;

(3) Providing appropriate training in containment and security procedures for all personnel in accordance with § 331.12;

(4) Transferring agents or toxins only to registered individuals or entities in accordance with § 331.13;

(5) Ensuring that all visitors are informed of and follow the entity's security requirements and procedures;

(6) Notifying APHIS of changes in circumstances in accordance with § 331.6;

(7) Providing timely notice of any theft, loss, or release of a biological agent or toxin in accordance with § 331.16;

(8) Maintaining detailed records of information necessary to give a complete accounting of all of the activities related to agents or toxins listed in § 331.3 in accordance with § 331.14.

(b) In addition to the requirements in paragraph (a) of this section, the responsible official for a diagnostic laboratory or other entity possessing, using, or transferring agents or toxins listed in § 331.3 that are contained in specimens presented for diagnosis must immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law.[7] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting.

§ 331.10 Restricting access to biological agents and toxins.

(a) An individual may not have access to biological agents or toxins listed in § 331.3 unless approved by APHIS. APHIS will grant, limit, or deny access of individuals to listed agents or toxins.

(b) The responsible official is responsible for ensuring that only approved individuals within the entity have access to any agents or toxins listed in § 331.3. The responsible official

[7] A diagnostic laboratory or other person must immediately notify APHIS by calling (301) 734–5519.

must request such access for only those individuals who have a legitimate need to handle or use listed agents or toxins, and who have the appropriate training and skills to handle such agents or toxins.

(c) The responsible official must provide appropriate training in containment and security procedures to all individuals with access to agents and toxins listed in § 331.3, in accordance with § 331.12.

(d) For each individual identified by the responsible official as having a legitimate need to handle or use listed agents or toxins, the responsible official must submit that individual's name and identifying information to APHIS and the Attorney General.

(e) In addition, the responsible official must submit information about the individual's training and skills to APHIS (e.g., curriculum vitae for principal investigators and researchers, and a description of training completed by support personnel).

(f) APHIS may expedite the access approval process for individuals upon request by the responsible official and a showing of good cause (e.g., agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher).

(g) APHIS will notify the responsible official if an individual is granted full or limited access, or denied access to listed agents or toxins. APHIS will also notify the individual if he/she is denied access or granted only limited access.

(h) APHIS may deny or limit access of an individual to listed agents or toxins if:

(1) The Attorney General identifies the individual as within any of the categories described in 18 U.S.C. 175b;

(2) The Attorney General identifies the individual as reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C.

2332b(g)(5); knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801;

(3) The individual does not have a legitimate need to handle listed agents or toxins;

(4) The individual does not have the necessary training or skills to handle listed agents or toxins;

(5) The Administrator determines that such action is necessary to protect plant health or plant products.

(i) An individual may appeal the Administrator's decision to deny or limit access under § 331.15.

(j) Access approval is valid for 5 years; thereafter, the responsible official shall request renewal of access approval every 5 years for as long as the individual needs access to agents or toxins listed in § 331.3.

(k) The responsible official must immediately notify APHIS when an individual's access to listed agents or toxins is terminated by the entity and the reasons therefore.

§ 331.11 Biocontainment and security plan.

(a) As a condition of registration, an individual or entity must develop and implement a Biocontainment and Security Plan.[8] The Biocontainment and Security Plan must contain sufficient information and documentation to describe the containment procedures and the security systems and procedures. The plan must be commensurate with the risk of the agent or toxin, given its intended use.

[8] Technical assistance and guidance may be obtained by calling (301) 734-5519.

(1) Containment procedures. The containment procedures must be sufficient to contain the agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). At a minimum, the plan must address containment and inventory control.

(2) Security systems and procedures.[9] The security systems and procedures must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the threat posed by the agent or toxin.

(i) The site-specific risk assessment should involve a threat assessment and risk analysis in which threats are defined, vulnerabilities examined, and risks associated with those vulnerabilities are identified.

(ii) The security systems and procedures must be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs, and must mitigate the risks identified under paragraph (a)(2)(i) of this section.

(iii) The plan must describe inventory control procedures, personnel suitability for those individuals with access to agents or toxins listed in § 331.3, physical security, and cybersecurity. The plan must also contain provisions for securing the area (e.g., card access, key pads, locks) and protocols for changing access numbers or locks following staff changes; procedures for loss or compromise of keys, passwords, combinations, etc.; procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or

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[9] For guidance, see the USDA Departmental Manual No. 9610-001, "USDA Security Policies and Procedures for Biosafety Level-3 Facilities" (August 30, 2002). The manual may be obtained by calling (301) 734-5519. The manual is also available on the Internet at http://www.usda.gov/ocio/directives/DM/DM9610-001.htm. See also Appendix F, "Biosafety in Microbiological and Biomedical Laboratories," in Morbidity and Mortality Weekly Report (2002). This document may be obtained by writing to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333. It is also available on the Internet at http://www.cdc.gov/mmwr.

alteration of inventory records; provisions for the control of access to containers where listed agents and toxins are stored; provisions for routine cleaning, maintenance, and repairs; and procedures for reporting and removing unauthorized persons.

(iv) With respect to areas containing listed agents or toxins, an entity or individual must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

(A) Allow unescorted access only to approved individuals who are performing a specifically authorized function during hours required to perform that job;

(B) Allow individuals not approved under § 331.10 to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually monitored by approved individuals;

(C) Provide for the control of access to containers where listed agents and toxins are stored by requiring that such containers be locked when not in the direct view of an approved individual and by using other monitoring measures, as needed;

(D) Require the inspection of all packages upon entry and exit;

(E) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging and movement, is conducted under the supervision of an approved individual;

(F) Require that approved individuals do not share with any other person their unique means of accessing the area or listed agents or toxins; and

(G) Require that approved individuals immediately report any of the following to the responsible official:

(1) Any loss or compromise of keys, passwords, combinations, etc.;

(2) Any suspicious persons or activities;

(3) Any loss or theft of listed agents or toxins;

(4) Any release of a listed agent or toxin; and

(5) Any sign that inventory and use records for listed agents and toxins have been altered or otherwise compromised.

(3) Incident response procedures.[10] The Biocontainment and Security Plan must also include incident response plans for containment breach, security breach, inventory violations, non-biological incidents such as workplace violence, and cybersecurity breach. The incident response plans must address containment, inventory control, and notification of managers and responders. The incident response plans must also address such events as bomb threats, severe weather (floods, hurricanes, tornadoes), earthquakes, power outages, and other natural disasters or emergencies.

(b) The Biocontainment and Security Plan must be reviewed, performance tested, and updated annually. The plan must also be reviewed and revised, as necessary, after any incident.

§ 331.12 Training.

(a) The responsible official must provide appropriate training in containment and security procedures to all individuals with access to agents and toxins listed in § 331.3.

(b) The responsible official must provide information and training to an individual at the time the individual is assigned to work with a listed agent or toxin. The responsible official must provide refresher training annually.

[10] The requirements in this paragraph do not supercede or preempt the enforcement of emergency response requirements imposed by other statutes or regulations.

§ 331.13 Transfer of biological agents and toxins.

Biological agents and toxins listed in § 331.3 may only be transferred to an individual or entity registered to possess, use, or transfer that particular agent or toxin. However, the sender of an agent or toxin may be an individual or entity that has a certificate of registration for the agent or toxin, an individual or entity that is exempt from the requirements of this part, or an individual or entity located outside of the United States. Biological agents or toxins may only be transferred under the conditions of this section and must be authorized by APHIS prior to the transfer.

(a) Importation and interstate movement. In addition to the permit required under part 330 of this chapter, biological agents or toxins listed in § 331.3 may be imported or moved interstate only with the prior authorization of APHIS. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS, in accordance with paragraph (c) of this section.

(b) Intrastate movement. Biological agents or toxins listed in § 331.3 may be moved intrastate only with the prior authorization of APHIS. To obtain authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS prior to each transfer, in accordance with paragraph (c) of this section.

(c) APHIS Form 2041; process and procedures.

(1) Prior to each transfer, the sender and the responsible official for the recipient must complete APHIS Form 2041, and the sender must submit the form to APHIS.[11]

[11] APHIS Form 2041 may be obtained by calling (301) 734-5519 or faxing a request to (301) 734-8700. The form is also available on the Internet at http://www.aphis.usda.gov/ppq/permits. APHIS Form 2041 may be mailed to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236; or faxed to (301) 734-8700.

(2) APHIS will authorize the transfer based on a finding that the recipient has a certificate of registration covering the transfer of the listed agent or toxin.

(3) The responsible official for the recipient entity must notify APHIS and the sender upon receipt of the agent or toxin by mailing or faxing a completed APHIS Form 2041 within 2 business days.

(4) The responsible official for the recipient must notify APHIS immediately if the agent or toxin has not been received within 48 hours after the expected delivery or if the package containing the agent or toxin is leaking or has been damaged.

(d) The sender must comply with all applicable laws governing packaging and shipping.

§ 331.14 Records.

(a) The responsible official must maintain complete, up-to-date records of information necessary to give an accounting of all of the activities related to agents or toxins listed in § 331.3. Such records must include the following:

(1) The Biocontainment and Security Plan;

(2) A current list of all individuals with access to agents or toxins listed in § 331.3;

(3) Training records for individuals with access to such agents or toxins;

(4) Accurate and current inventory records (including source and characterization data);

(5) Permits and transfer documents (APHIS Form 2041) issued by APHIS;

(6) Security records (e.g., transactions from automated access control systems, testing and maintenance of security systems, visitor logs); and

(7) Containment and security incident reports.

(b) The responsible official must maintain such records for 3 years.

(c) All records must be produced upon request to APHIS inspectors, and appropriate Federal, State, or local law enforcement authorities.

§ 331.15 Inspections.

(a) To ensure compliance with the regulations, any APHIS inspector must be allowed, without previous notification, to enter and inspect the entire premises, all materials and equipment, and all records required to be maintained by this part.

(b) Prior to issuing a certificate of registration to an entity or individual, APHIS may inspect and evaluate their premises and records to ensure compliance with the regulations and the containment and security requirements.

§ 331.16 Notification in the event of theft, loss, or release of a biological agent or toxin.

(a) The responsible official must orally notify APHIS and appropriate Federal, State, or local law enforcement agencies immediately upon discovery of the theft or loss of agents or toxins listed in § 331.3. The oral notification must be followed by a written report (APHIS Form 2043) within 7 days.

(b) The responsible official must orally notify APHIS immediately upon discovery that a release of an agent or toxin has occurred outside of the biocontainment area. The oral notification must be followed by a written report (APHIS Form 2043) within 7 days. Upon notification and a finding that the release poses a threat to animal or plant health, or animal or plant products, APHIS will notify relevant Federal, State, and local authorities, and the public, if necessary.

(c) The responsible official must orally notify APHIS of a theft, loss, or release of an agent or toxin by calling (301) 734-5519. A copy of APHIS Form 2043 may be obtained by writing to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133,

Riverdale, MD 20737-1236, or by calling (301) 734-5519. APHIS Form 2043 may be mailed to the same address or faxed to (301) 734-8700.

§ 331.17 Administrative review.

An individual or entity may appeal a denial or revocation of registration under this part. An individual who has been denied access to listed agents or toxins or who has been granted only limited access to listed agents or toxins under this part may appeal that decision.[12] The appeal must be in writing and submitted to the Administrator within 30 days of the decision. The appeal must state all of the facts and reasons upon which the individual or entity disagrees with the decision. Where the denial or revocation of registration or the denial or limitation of an individual's access approval is based solely upon an identification by the Attorney General, APHIS will forward the request for review to the Attorney General. The Administrator's decision constitutes final agency action.

9 CFR Chapter I

PART 121—POSSESSION, USE, AND TRANSFER OF BIOLOGICAL AGENTS AND TOXINS

Sec.

[12] An entity may not appeal the denial or limitation of an individual's access to listed agents or toxins.

Authority: Secs. 211-213, Title II, Pub. L. 107-188, 116 Stat. 647 (7 U.S.C. 8401).

§ 121.0 Effective and applicability dates.

The regulations in this part are effective on [Insert date 60 days after date of publication in the Federal Register]. On and after that date, any person possessing, using, or transferring any agent or toxin listed in § 121.3 must be in compliance with the provisions of this part. However, so as not to disrupt research or educational projects involving listed agents or toxins that were underway as of the effective date of this part, any person possessing such agents or toxins as of the effective date (current possessors) will be afforded additional time to reach full compliance with this part. Any provision not specifically cited in paragraphs (a) through (f) of this section will be applicable as of [Insert date 60 days after date of publication in the Federal Register]. In addition, any person who does not possess listed agents or toxins by the effective date of this part, but who wishes to initiate a research or educational project prior to November 12, 2003, must be in compliance with the provisions of this part that are applicable for current possessors at the time of application, as provided in paragraphs (a) through (e) of this section.

(a) During the period from [Insert date 60 days after date of publication in the Federal Register], to November 12, 2003, biological agents or toxins listed in § 121.3 may only be transferred to an individual or entity that is not registered under this part if:

(1) The individual or entity is registered by CDC for that specific overlap agent or toxin in accordance with 42 CFR part 72; or

(2) The individual or entity has been issued a permit by the Administrator under part 122 of this subchapter to import or move interstate that specific agent or toxin. If an individual or entity has not been issued a permit under part 122 of this subchapter, the individual or entity may apply for a permit. To receive an agent or toxin, an individual or entity will also be required to submit APHIS Form 2041, in accordance with § 121.14(c). Because USDA permits do not cover intrastate movement, unless registered by CDC under 42 CFR part 72, an individual or entity may not receive a listed agent or toxin that is being moved intrastate until that individual or entity is registered in accordance with this part.

(b) By March 12, 2003, the responsible official must submit the registration application package as required in § 121.9. In addition, the responsible official must submit to the Attorney General the names and identifying information for the responsible official; alternate responsible official, where applicable; entity; and, where applicable, the individual who owns or controls the entity.

(c) By April 11, 2003, the responsible official must submit to the Attorney General the names and identifying information for all individuals whom the responsible official has identified as having a legitimate need to handle or use listed agents or toxins, and who have the appropriate training and skills to handle such agents or toxins, as required in § 121.11.

(d) By June 12, 2003, the responsible official must submit the security section of the Biosafety and Security Plan required in § 121.12 to APHIS or, for overlap agents or toxins, to APHIS or CDC.

(e) By September 12, 2003, the responsible official must implement the security section of the Biosafety and Security Plan, as required in § 121.12, and provide security training in accordance with 9 CFR 121.13.

(f) By November 12, 2003, the registration application process must be complete and the entity in full compliance with the regulations in this part.

§ 121.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Attorney General. The Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

Clinical laboratory. A laboratory facility that receives patients and collects specimens for processing or shipping to another laboratory.

Diagnostic laboratory. A laboratory facility that receives specimens for the purpose of determining the identities of pests, pathogens, contaminants, or causes of disease.

Entity. Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

Import. To move into, or the act of movement into, the territorial limits of the United States.

Interstate. From one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Overlap agent or toxin. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) or toxin that poses a risk to both human and animal health and that is listed in § 121.3(b).

Permit. A written authorization by the Administrator to import or move interstate biological agents or toxins, under conditions prescribed by the Administrator.

Proficiency testing. A sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated for acceptance.

Responsible official. The individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this part.

Specimen. A sample of material collected for use in testing, such as tissues, gastrointestinal contents, feces, bodily fluids (blood, serum, etc.), soil, water, feed or feed ingredients, swabs, cultures, and suspensions.

State. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States. All of the States.

USDA. The United States Department of Agriculture.

§ 121.2 Purpose and scope.

(a) This part sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products. The purpose of this part is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose.

(b) Accordingly, this part provides that any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 121.3 must register in accordance with § 121.7. To register, each entity must designate an individual who has the authority and control to ensure compliance with the regulations to be the responsible official. The responsible official must

complete and submit the registration application package to APHIS or, for overlap agents or toxins, to APHIS or CDC. As part of registration, the responsible official, the entity, and, where applicable, the individual who owns or controls such entity will be subject to a security risk assessment by the Attorney General.

(c) The responsible official is responsible for ensuring compliance with the safety procedures in this part, including implementing the Biosafety and Security Plan in accordance with § 121.12, providing the proper training to individuals who handle or use agents or toxins listed in § 121.3, and providing proper laboratory facilities to contain and dispose of such agents or toxins. In addition, the responsible official is responsible for ensuring compliance with the safeguard and security measures in this part, including restricting access to only those individuals who have a legitimate need to handle or use agents or toxins and who have been approved in accordance with § 121.11, and transferring such agents or toxins only to registered individuals or entities in accordance with § 121.13.

§ 121.3 List of biological agents and toxins.

(a) Except as provided in paragraphs (f) and (g) of this section, the Administrator has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products.

(b) Overlap agents and toxins.

Bacillus anthracis
Botulinum neurotoxins
Botulinum neurotoxin producing species of Clostridium
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei
Burkholderia pseudomallei
Clostridium botulinum
Clostridium perfringens epsilon toxin

Coccidioides immitis
Coxiella burnetii
Eastern equine encephalitis virus
Francisella tularensis
Hendra virus
Nipah virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Venezuelan equine encephalitis virus

(c) Genetic elements, recombinant nucleic acids, and recombinant organisms of overlap agents or toxins:

(1) Biological agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the biological agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (b) of this section, if the nucleic acids:

(i) Are in a vector or host chromosome;

(ii) Can be expressed in vivo or in vitro ; or

(iii) Are in a vector or host chromosome and can be expressed in vivo or in vitro.

(3) Viruses, bacteria, fungi, and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Animal agents and toxins.

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus

Cowdria ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus (exotic)
Menangle virus
Mycoplasma capricolum /M. F38/M. mycoides capri (contagious caprine pleuropneumonia)
Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia)
Newcastle disease virus (VVND)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic)

(e) The Administrator has determined that it would be impractical to regulate a biological agent or toxin that is in its naturally occurring environment. Therefore, any biological agent or toxin listed in this section that is in its naturally occurring environment will not be subject to the requirements of this part, provided that the biological agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(f) The Administrator has determined that biological agents or toxins that meet any of the following criteria do not have the potential to pose a severe threat to both human and animal health, or to animal health or animal products. Therefore, an individual or entity that only possesses, uses, or transfers an agent or toxin that meets any of the following criteria will not be subject to the requirements of this part:

(1) Nonviable agents or fixed tissues that are, bear, or contain agents or toxins listed in this section.[1]

[1] However, the importation and interstate movement of these genetic elements or subunits of listed agents or toxins are still subject to the permit requirements under part 122 of this subchapter.

(2) Genetic elements or subunits of agents or toxins listed in paragraph (d) of this section, if the genetic elements or subunits are not capable of causing disease.[2]

(3) Overlap toxins under the control of a principal investigator (or equivalent), if the total aggregate amount does not, at any time, exceed the following amounts: 0.5 mg of Botulinum neurotoxins (types A-G), 100 mg of Clostridium perfringens epsilon toxin, 100 mg of Shigatoxin, 5 mg of Staphylococcal enterotoxins, and 1,000 mg of T-2 toxin.

(g) Attenuated strains. Attenuated strains of biological agents listed in this section may not have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products. Thus, an individual or entity may request review by the Administrator to determine whether a specific attenuated strain poses a severe threat to both human and animal health, or to animal health or animal products. For overlap agents, an individual or entity may request review by APHIS or CDC.

(1) If APHIS or CDC determines that a specific attenuated strain does not pose a severe threat to human and animal health, or to animal health or animal products, an individual or entity will not be subject to the requirements of this part. This determination will be limited to the specific attenuated strain and to the specific activities involving that attenuated strain.

(2) An individual or entity may request a review by writing to the Administrator or, for overlap agents, by writing to the Administrator or CDC.[3]

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[2] See footnote 1.

[3] A request to review an attenuated strain may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652. For overlap agents, a request for review may be mailed to the above address or to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333; or faxed to (404) 498-2265.

(3) If it is determined that a specific attenuated strain does not pose a severe threat, APHIS or CDC will notify the applicant and publish a notice in the Federal Register.

(4) An individual or entity may request reconsideration of an adverse decision in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies upon to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.

§ 121.4 Exemptions for overlap agents or toxins.

(a) Clinical or diagnostic laboratories and other entities possessing, using, or transferring overlap agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins is immediately reported to APHIS or CDC, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 7 days after identification, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to APHIS or CDC.[4] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. A copy of the completed form must be maintained for 3 years.

[4] A clinical or diagnostic laboratory, or other entity, may immediately notify APHIS by faxing (301) 734-3652. APHIS Form 2040 may be obtained by calling APHIS at (301) 734-3277 or by calling CDC at (404) 498-2265. The form is also available on the Internet at http://www.aphis.usda.gov/vs/ncie.bta.html or http://www.cdc.gov/od/ohs/lrsat.htm. The completed form may be mailed or faxed to APHIS or CDC, as provided in footnote 3.

(b) Clinical or diagnostic laboratories and other entities possessing, using, or transferring overlap agents or toxins that are contained in specimens presented for proficiency testing will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins, and their derivatives, is immediately reported to the APHIS or CDC, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 90 days of receipt, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to APHIS or CDC. A copy of the completed form must be maintained for 3 years.

(c) Unless the Administrator by order determines that additional regulation of a specific product is necessary to protect animal or plant health, or animal or plant products, an individual or entity possessing, using, or transferring products that are, bear, or contain overlap agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151-159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 et seq.).

(d) An individual or entity possessing, using, or transferring investigational products that are, bear, or contain overlap agents or toxins may be exempt from the requirements of this part if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal or plant health, and animal or plant products.

(1) An individual or entity possessing, using, or transferring such investigational products may apply for an exemption from the requirements of this part by submitting APHIS Form 2042 to APHIS or CDC.

(2) For investigational products authorized under any of the Federal laws specified in paragraph (c) of this section, the Administrator shall make a determination regarding an exemption within 14 days after receipt of the application and notification that the investigation has been authorized under a Federal law.

(e) The Administrator may exempt an individual or entity from the requirements of this part, in whole or in part, for 30 days if it is necessary to respond to a domestic or foreign agricultural emergency involving an overlap agent or toxin. The Administrator may extend the exemption once for an additional 30 days.

(f) Upon request of the Secretary of Health and Human Services, the Administrator may exempt an individual or entity from the requirements of this part, in whole or in part, for 30 days if the Secretary of Health and Human Services has granted an exemption for a public health emergency involving an overlap agent or toxin. The Administrator may extend the exemption once for an additional 30 days.

§ 121.5 Exemptions for animal agents and toxins.

(a) Diagnostic laboratories and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins is immediately reported to the Administrator and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 7 days after identification, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator.[5] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. A copy of the completed form must be maintained for 3 years.

(b) Diagnostic laboratories and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for proficiency testing will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins, and their derivatives, is immediately reported to the Administrator, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 90 days of receipt, the agent or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator. A copy of the completed form must be maintained for 3 years.

(c) An individual or entity receiving diagnostic reagents and vaccines that are, bear, or contain listed agents or toxins, also known as high consequence livestock pathogens or toxins, that are produced at USDA diagnostic facilities will be exempt from the requirements of this part.

(d) Unless the Administrator by order determines that additional regulation is necessary to protect animal health or animal products, an individual or entity possessing, using, or transferring products that are, bear, or contain listed agents or toxins will be exempt from the

[5] A diagnostic laboratory or other entity must immediately notify APHIS by faxing (301) 734-3652. APHIS Form 2040 may be obtained by calling (301) 734-3277. The form is also available on the Internet at http://www.aphis.usda.gov/vs/ncie.bta.html. The completed form may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652.

requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151-159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 et seq.).

(e) An individual or entity possessing, using, or transferring experimental products that are, bear, or contain listed agents or toxins may be exempt from the requirements of this part if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal or plant health, and animal or plant products. An individual or entity possessing, using, or transferring such experimental products may apply for an exemption from the requirements of this part by submitting APHIS Form 2042 to APHIS.

(f) In addition to the exemptions provided in paragraphs (a) through (e) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal health and animal products. An individual or entity that possesses, uses, or transfers agents or toxins may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances

allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.[6]

§ 121.6 Registration; who must register.

(a) Unless exempted under §§ 121.4 or 121.5, any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 121.3 must register with APHIS or, for overlap agents or toxins, APHIS or CDC.

(b) Each entity must designate an individual to be its responsible official. The responsible official must have the authority and control to ensure compliance with the regulations. The responsible official must complete and sign the registration application package, and will be the individual contacted by APHIS or CDC if any questions arise concerning the application or subsequent compliance with the regulations in this part. As part of registration, the responsible official and the entity will be subject to a security risk assessment by the Attorney General. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, APHIS will consider the individual to be the responsible official.

(c) An entity may designate one or more individuals to be an alternate responsible official, who may act for the responsible official when he/she is unavailable. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official. These individuals will also be subject to a security risk assessment by the Attorney General as part of registration.

[6] A request for exemption may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652.

§ 121.7 Registration; general provisions.

(a) Unless exempted under §§ 121.4 or 121.5, an individual or entity shall not possess, use, or transfer any agent or toxin listed in § 121.3 without a certificate of registration issued by APHIS or CDC.

(b) A certificate of registration may be issued upon:

(1) Approval of the responsible official; the alternate responsible official, where applicable; the entity; and, where applicable, the individual who owns or controls the entity following a security risk assessment by the Attorney General;[7] and

(2) Approval of the biosafety, containment, and security of the entity. The entity's biosafety, containment, and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS or CDC will review the Biosafety and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the biosafety, containment, and security requirements; and

(3) A determination by the Administrator that the individual or entity seeking to register has a lawful purpose to possess, use, or transfer such agents or toxins.

(c) For overlap agents, APHIS and CDC will review applications for registration and amendments to a certificate of registration, and a certificate of registration or amendment to a certificate of registration will only be issued if APHIS and CDC concur.

(d) A certificate of registration will be valid for only the specific agents or toxins listed in the certificate and specific activities and locations. A certificate of registration may cover

[7] The security risk assessment of the entity and the individual who owns or controls such entity may be waived for Federal, State, or local governmental agencies.

more than one listed agent or toxin, and it may be amended to cover additional listed agents or toxins.

(e) A certificate of registration may be amended to reflect changed circumstances (e.g., replacement of the responsible official, changes in ownership or control of the entity,[8] changes in the activities involving the agent or toxin). The responsible official must immediately notify the agency that issued the certificate of registration, either APHIS or CDC, of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

(f) If a responsible official wishes to discontinue possessing, using, or transferring a particular agent or toxin, the responsible official may inactivate the agent or toxin or he/she may transfer the agent or toxin to a registered individual or entity in accordance with § 121.13. The responsible official must notify APHIS or, for overlap agents or toxins, APHIS or CDC, 5 business days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. APHIS or CDC will notify the responsible official if we wish to observe the inactivation of the agents or toxins.

(g) A certificate of registration will be valid for a maximum of 3 years.

§ 121.8 Denial, revocation, or suspension of registration.

(a) APHIS may deny an application for registration or revoke registration if:

(1) The Attorney General identifies the responsible official, entity, or individual who owns or controls the entity as within any of the categories described in 18 U.S.C. 175b; or

[8] Any change in ownership or control of an entity will require a security risk assessment for the new individual(s) who owns or controls the entity.

(2) The Attorney General identifies the responsible official, entity, or individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime set forth in 18 U.S.C. 2332b(g)(5); or

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) The responsible official does not have a lawful purpose to possess, use, or transfer agents or toxins listed in § 121.3; or

(4) The responsible official is an individual who handles or uses agents or toxins listed in § 121.3 and he/she does not have the necessary training or skills to handle such agents or toxins; or

(5) The entity does not meet the biosafety, containment, and security requirements prescribed by the Administrator;[9] or

(6) There are egregious or repeated violations of the biosafety, containment, or security requirements; or

(7) The Administrator determines that such action is necessary to protect animal or plant health, and animal or plant products.

(b) For overlap agents or toxins, APHIS or CDC shall deny an application for registration or revoke registration if the Attorney General identifies the responsible official, entity, or individual who owns or controls the entity as within any of the categories described in

[9] If registration is denied for this reason, we may provide technical assistance and guidance.

18 U.S.C. 175b. APHIS or CDC may also deny registration or revoke registration for the reasons set forth in paragraphs (a)(2) through (a)(7) of this section.

(c) APHIS may summarily revoke or suspend registration for any of the reasons set forth in paragraphs (a) and (b) of this section.

(d) APHIS will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended. For overlap agents or toxins, APHIS or CDC will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended.

(e) Denial of an application for registration, revocation of registration, and suspension of registration may be appealed under § 121.17.

§ 121.9 Registration; how to register.

(a) To apply for a certificate of registration, the responsible official must submit all of the information and documentation required in the registration application package to APHIS, including the name, source, and characterization data for each agent or toxin to be registered. For overlap agents or toxins, the responsible official must submit all of the information and documentation required in the registration package to either APHIS or CDC. The responsible official must submit the registration application package to APHIS in cases where he/she is seeking registration for both animal and overlap agents and toxins.

(b) For animal agents and toxins, the registration application package may be obtained by calling (301) 734-3277 or faxing a request to (301) 734-3652. It is also available on the Internet at http://www.aphis.usda.gov/vs/ncie.bta.html. The completed registration application package must be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road

Unit 40, Riverdale, MD 20737-1231. Assistance in completing the registration application may be requested by calling (301) 734-3277.

(c) For overlap agents and toxins, the registration application package may be obtained by contacting APHIS, as set forth in paragraph (b) of this section, or by calling CDC at (404) 498-2255; faxing a request to (404) 498-2265; or writing to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333. It is also available on the Internet at http://www.cdc.gov/od/ohs/lrsat.htm. The completed registration application package may be mailed to APHIS at the address provided in paragraph (b) of this section or to CDC's Select Agent Program at the address provided in this paragraph. Assistance in completing the registration application may be requested by calling APHIS or CDC at the telephone numbers provided in this section.

§ 121.10 Responsibilities of the responsible official.

(a) The responsible official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing a Biosafety and Security Plan in accordance with § 121.12;

(2) Allowing only approved individuals within the entity to have access to any agents or toxins listed in § 121.3 in accordance with § 121.11;

(3) Providing appropriate training in biosafety, containment, and security procedures for all personnel in accordance with § 121.13;

(4) Transferring agents or toxins only to registered individuals or entities in accordance with § 121.14;

(5) Ensuring that all visitors are informed of and follow the entity's security requirements and procedures;

(6) Notifying APHIS or, for overlap agents or toxins, APHIS or CDC, of changes in circumstances in accordance with § 121.7;

(7) Providing timely notice of any theft, loss, or release of a biological agent or toxin in accordance with § 121.17;

(8) Maintaining detailed records of information necessary to give a complete accounting of all of the activities related to agents or toxins listed in § 121.3 in accordance with § 121.15.

(b) In addition to the requirements in paragraph (a) of this section, the responsible official for a diagnostic laboratory or other entities possessing, using, or transferring agents or toxins listed in § 121.3 that are contained in specimens presented for diagnosis must immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law.[10] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting.

(c) In addition to the requirements in paragraph (a) of this section, the responsible official must ensure that the following experiments are not conducted unless approved by the Administrator, after consultation with experts:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a pathogenic trait or drug resistance trait to biological agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

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[10] A diagnostic laboratory or other entity must immediately notify APHIS by faxing (301) 734–3652.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD_{50}<100 ng/kg body weight.

§ 121.11 Restricting access to biological agents and toxins.

(a) An individual may not have access to biological agents or toxins listed in § 121.3 unless approved by APHIS or CDC. APHIS will grant, limit, or deny access of individuals to listed agents or toxins. APHIS or CDC will grant, limit, or deny access of individuals to overlap agents or toxins.

(b) The responsible official is responsible for ensuring that only approved individuals within the entity have access to any agents or toxins listed in § 121.3. The responsible official must request such access for only those individuals who have a legitimate need to handle or use agents or toxins, and who have the appropriate training and skills to handle such agents or toxins. (c) The responsible official must provide appropriate training in biosafety, containment, and security procedures to all individuals with access to agents and toxins listed in § 121.3.

(d) For each individual identified by the responsible official as having a legitimate need to handle or use agents or toxins, the responsible official must submit that individual's name and identifying information to APHIS and the Attorney General. For overlap agents or toxins, the responsible official must submit this information to either APHIS or CDC and the Attorney General.

(e) In addition, the responsible official must submit information about the individual's training and skills to APHIS or, for overlap agents or toxins, APHIS or CDC (e.g., curriculum vitae for principal investigators and researchers, and a description of training completed by support personnel).

(f) APHIS may expedite the access approval process for individuals upon request by the responsible official and a showing of good cause (e.g., public health or agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher).

(g) APHIS will notify the responsible official if an individual is granted full or limited access, or denied access to listed agents or toxins. APHIS will also notify the individual if he/she is denied access or granted only limited access. For overlap agents or toxins, APHIS or CDC will provide the necessary notification.

(h) APHIS may deny or limit access of an individual to listed agents or toxins if:

(1) The Attorney General identifies the individual as within any of the categories described in 18 U.S.C. 175b;

(2) The Attorney General identifies the individual as reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5); knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801;

(3) The individual does not have a legitimate need to handle listed agents or toxins;

(4) The individual does not have the necessary training or skills to handle listed agents or toxins;

(5) The Administrator determines that such action is necessary to protect animal health or animal products.

(i) For overlap agents or toxins, APHIS or CDC will deny an individual access to such agents or toxins if the Attorney General identifies the individual as within any of the categories described in 18 U.S.C. 175b. APHIS or CDC may also deny or limit access of an individual for the reasons set forth in paragraphs (f)(2) through (f)(5) of this section.

(j) An individual may appeal the Administrator's decision to deny or limit access under § 121.17.

(k) Access approval is valid for 5 years; thereafter, the responsible official shall request renewal of access approval every 5 years for as long as the individual needs access to agents or toxins listed in § 121.3.

(l) The responsible official must immediately notify APHIS or, for overlap agents or toxins, APHIS or CDC, when an individual's access to agents or toxins listed in § 121.3 is terminated by the entity and the reasons therefore.

§ 121.12 Biosafety and security plan.

(a) As a condition of registration, the responsible official must develop and implement a Biosafety and Security Plan.[11] The Biosafety and Security Plan must contain sufficient information and documentation to describe the biosafety and containment procedures, and the security systems and procedures. The plan must be commensurate with the risk of the agent or toxin, given its intended use.

(1) Biosafety and containment procedures.[12] The biosafety and containment procedures must be sufficient to contain the agent or toxin (e.g., physical structure and features of the entity,

[11] Technical assistance and guidance may be obtained by calling (301) 734-3277.

[12] For guidance on biosafety and containment procedures, see the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories" (4th ed. 1999).

and operational and procedural safeguards). At a minimum, the plan must address containment, personnel safety and health, and inventory control.

(2) Security systems and procedures.[13] The security systems and procedures must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the threat posed by the agent or toxin.

(i) The site-specific risk assessment should involve a threat assessment and risk analysis in which threats are defined, vulnerabilities examined, and risks associated with those vulnerabilities are identified.

(ii) The security systems and procedures must be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs and must mitigate the risks identified under paragraph (a)(2)(i) of this section.

(iii) The plan must describe inventory control procedures, personnel suitability for those individuals with access to agents or toxins listed in § 121.3, physical security, and cybersecurity. The plan must also contain provisions for routine cleaning, maintenance, and repairs; provisions for securing the area (e.g., card access, key pads, locks) and protocols for changing access numbers or locks following staff changes; procedures for loss or compromise of keys, passwords, combinations, etc.; procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or alteration of inventory

[13] For guidance, see the USDA Departmental Manual No. 9610-001, "USDA Security Policies and Procedures for Biosafety Level-3 Facilities" (August 30, 2002). The manual may be obtained by calling (301) 734-3277. The manual is also available on the Internet at http://www.usda.gov/ocio/directives/DM/DM9610-001.htm. See also Appendix F, "Biosafety in Microbiological and Biomedical Laboratories," in Morbidity and Mortality Weekly Report (2002). This document may be obtained by writing to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333. It is also available on the Internet at http://www.cdc.gov/mmwr.

records; provisions for the control of access to containers where listed agents and toxins are stored; and procedures for reporting and removing unauthorized persons.

(iv) With respect to areas containing listed agents or toxins, an entity or individual must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

(A) Allow unescorted access only to approved individuals who are performing a specifically authorized function during hours required to perform that job;

(B) Allow individuals not approved under § 121.11 to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually monitored by approved individuals;

(C) Provide for the control of access to containers where listed agents and toxins are stored by requiring that such containers be locked when not in the direct view of an approved individual and by using other monitoring measures, as needed;

(D) Require the inspection of all packages upon entry and exit;

(E) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging and movement, is conducted under the supervision of an approved individual;

(F) Require that approved individuals do not share with any other person their unique means of accessing the area or listed agents or toxins; and

(G) Require that approved individuals immediately report any of the following to the responsible official:

(1) Any loss or compromise of keys, passwords, combinations, etc.;

(2) Any suspicious persons or activities;

(3) Any loss or theft of listed agents or toxins;

(4) Any release of a listed agent or toxin; and

(5) Any sign that inventory and use records for listed agents and toxins have been altered or otherwise compromised.

(3) Incident response procedures.[14] The Biosafety and Security Plan must also include incident response plans for containment breach, security breach, inventory violations, non-biological incidents such as workplace violence, and cybersecurity breach. The incident response plans must address personnel safety and health, containment, inventory control, and notification of managers and responders. The incident response plans must also address such events as bomb threats, severe weather (floods, hurricanes, tornadoes), earthquakes, power outages, and other natural disasters or emergencies.

(b) The Biosafety and Security Plan must be reviewed, performance tested, and updated annually. The plan must also be reviewed and revised, as necessary, after any incident.

§ 121.13 Training.

(a) The responsible official must provide appropriate training in biosafety, containment, and security procedures to all individuals with access to agents and toxins listed in § 121.3.

(b) The responsible official must provide information and training to an individual at the time the individual is assigned to work with a listed agent or toxin. The responsible official must provide refresher training annually.

§ 121.14 Transfer of biological agents and toxins.

Biological agents and toxins listed in § 121.3 may only be transferred to individuals or entities registered to possess, use, or transfer that particular agent or toxin. However, the sender

[14] The requirements in this paragraph do not supercede or preempt the enforcement of emergency response requirements imposed by other statutes or regulations.

of an agent or toxin may be an individual or entity that has a certificate of registration for the agent or toxin, an individual or entity that is exempt from the requirements of this part, or an individual or entity located outside of the United States. Biological agents or toxins may only be transferred under the conditions of this section and must be authorized by APHIS or, for overlap agents or toxins, by APHIS or CDC, prior to the transfer.

(a) Importation and interstate movement. In addition to the permit required under part 122 of this subchapter, biological agents or toxins listed in § 121.3 may be imported or moved interstate only with the prior authorization of APHIS or, for overlap agents or toxins, APHIS or CDC. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS or CDC, in accordance with paragraph (c) of this section.

(b) Intrastate movement. Biological agents or toxins listed in § 121.3 may be moved intrastate only with the prior authorization of APHIS or, for overlap agents or toxins, APHIS or CDC. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS or CDC, in accordance with paragraph (c) of this section.

(c) APHIS Form 2041; process and procedures.

(1) Prior to each transfer, the responsible official for the recipient and sender must complete APHIS Form 2041, and the sender must submit the form to APHIS or, for overlap agents or toxins, to APHIS or CDC.[15]

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[15] APHIS Form 2041 may be obtained by calling APHIS at (301) 734-3277 or by calling CDC at (404) 498-2265. The form is also available on the Internet at http://www.aphis.usda.gov/vs/ncie.bta.html or http://www.cdc.gov/od/ohs/lrsat.htm. APHIS Form 2041 may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652. For overlap agents and toxins, it may be mailed to the above address or to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333;

(2) APHIS or CDC will authorize the transfer based on a finding that the recipient has a certificate of registration covering the transfer of the listed agent or toxin.

(3) The responsible official for the recipient must notify the agency authorizing the transfer (either APHIS or CDC) and the sender upon receipt of the agent or toxin by mailing or faxing a completed APHIS Form 2041 to APHIS or CDC within 2 business days.

(4) The responsible official for the recipient must notify APHIS or CDC immediately if the agent or toxin has not been received within 48 hours after the expected delivery or if the package containing the agent or toxin is leaking or has been damaged.

(d) The sender must comply with all applicable laws governing packaging and shipping.

§ 121.15 Records.

(a) The responsible official must maintain complete, up-to-date records of information necessary to give an accounting of all of the activities related to agents or toxins listed in § 121.3. Such records must include the following:

(1) The Biosafety and Security Plan;

(2) A current list of all individuals with access to agents or toxins listed in § 121.3;

(3) Training records for individuals with access to such agents or toxins;

(4) Accurate and current inventory records (including source and characterization data);

(5) Permits and transfer documents (APHIS Form 2041) issued by APHIS and CDC;

(6) Security records (e.g., transactions from automated access control systems, testing and maintenance of security systems, visitor logs);

(7) Biosafety, containment, and security incident reports.

(b) The responsible official must maintain such records for 3 years.

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or faxed to (404) 498-2265.

(c) All records must be produced upon request to APHIS or CDC inspectors, and appropriate Federal, State, or local law enforcement authorities.

§ 121.16 Inspections.

(a) To ensure compliance with the regulations, any APHIS or CDC inspector must be allowed, without previous notification, to enter and inspect the entire premises, all materials and equipment, and all records required to be maintained by this part.

(b) Prior to issuing a certificate of registration to an entity or individual, APHIS or CDC may inspect and evaluate the premises and records to ensure compliance with the regulations and the biosafety, containment, and security requirements.

§ 121.17 Notification in the event of theft, loss, or release of a biological agent or toxin.

(a) The responsible official must orally notify APHIS and appropriate Federal, State, or local law enforcement agencies immediately upon discovery of the theft or loss of agents or toxins listed in § 121.3. The oral notification must be followed by a written report (APHIS Form 2043) within 7 days.

(b) The responsible official must orally notify APHIS immediately upon discovery that a release of an agent or toxin has occurred outside of the biocontainment area. The oral notification shall be followed by a written report (APHIS Form 2043) within 7 days. Upon notification and a finding that the release poses a threat to animal or plant health, or animal or plant products, APHIS will notify relevant Federal, State, and local authorities, and the public, if necessary. If the release involves an overlap agent or toxin, APHIS will also notify the Secretary of Health and Human Services.

(c) The responsible official must orally notify APHIS of a theft, loss, or release of an agent or toxin by calling (866) 994-5698. A copy of APHIS Form 2043 may be obtained by

writing to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or by calling (301) 734-3277. The form is also available on the Internet at http://www.aphis.usda.gov/vs/ncie.bta.html. APHIS Form 2043 may be mailed to the same address or faxed to (301) 734-3652.

§ 121.18 Administrative review.

An individual or entity may appeal a denial or revocation of registration under this part. An individual who has been denied access to listed agents or toxins or who has been granted only limited access to listed agents or toxins under this part may appeal that decision.[16] The appeal must be in writing and submitted to the Administrator within 30 days of the decision. The appeal must state all of the facts and reasons upon which the individual or entity disagrees with the decision. Where the denial or revocation of registration or the denial or limitation of an individual's access approval is based solely upon an identification by the Attorney General, APHIS will forward the request for review to the Attorney General. The Administrator's decision constitutes final agency action.

Done in Washington, DC, this _____ day of _____ .

Under Secretary for Marketing and Regulatory Programs.

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[16] An entity may not appeal the denial or limitation of an individual's access to listed agents or toxins.